

Notified Body or Certification Body?

With Martin Tettke, Prof. Dr. Christian Johner

Audio File: [ZERTIFIZIERUNG 1.MP3](#)



Transcript

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The big advantage of the approach we discussed before is that once I'm in the 13485, I have booked the notified body almost immediately, because we certainly won't be a manufacturer, we can't let that fall down, who already has a 13485 with us.

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Medical Device Insights, a podcast by the Johner Institute for medical device manufacturers, authorities and notified bodies.

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The evaluation of the MDR is now pending.

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That is, now, if we think about it again, we have a

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good regulation was built for us, which was helpful for this whole market.

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It was the problems that one might want to solve in a revision with it.

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Now there are many companies that have not yet completed this path through the MDR.

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This means that there are companies that want to put a product on the market for the first time, of course under the umbrella of an MDR.

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And these companies are often faced with the question,

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K., do I need a notified body now?

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Do I need a certifier?

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When should I include them?

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Yes, that can be too early or too late.

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And I think the best way to clarify such questions is to ask a certifier and a notified body directly.

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And that's exactly what we're doing today and I've invited Martin Tätke to do it.

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Martin Tätke works at Berlin Zert and has been for many, many years.

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Of course, the first question you ask yourself is how you get a

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such an unnamed body.

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Martin, what was your path, how did you get there and what tasks do you have today at this designated

body, at this certifier?

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Yes, hello Christian, first of all, thank you very much for the invitation.

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I've been with Bernizer for over 10 years now, I studied mechanical engineering myself in the field of medical technology, was researching in the field of medical devices, software development for 6 years and then actually happened to be in this area of certification

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stumbled.

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I have to say, I enjoy it a lot, because I actually come from the field of software development and cyber-security myself and these are now one of my main tasks at Berlin Zeit.

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and of course you are confronted with many companies or is perhaps the wrong term.

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You are happy about many companies that come to you and that want to be accompanied by you through this path.

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That is, companies for which it is important that they can legally sell their products afterwards

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and of course the requirements of M.

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be fulfilled.

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And there are now always the topics of accreditation or certification.

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Can you help us to get clarity then?

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So, what exactly do these companies need?

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Yes, very much.

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Basically, this mainly affects young companies that are just entering the field of medical devices, in the process of developing a product that I personally particularly enjoy, because they are often the very innovative companies.

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Let's start with the area of naming.

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A notified body is an organisation that has been designated or notified by the European Commission and is regulated in accordance with European regulations in the field of M.

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then, for example, allow a manufacturer to place a product on the market after various tests.

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A company can only turn to a notified body at the moment when the product is ready.

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This means that this includes both the product itself and the complete

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technical documentation including clinical evaluation.

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This means that the notified body may only take action when the product is ready.

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The situation is a little different with the certification body.

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Certification bodies in Germany are accredited by the DAX, i.e. it is a national accreditation that can be obtained via E.

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but then also applies throughout Europe.

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Accreditation, accredited bodies are generally active in the field of standards.

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We are talking about the

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13485, i.e. the standard for quality management systems for medical devices, applies not only to manufacturers, but also to service providers in the field.

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This means that, for the first time, it has a larger scope than a designation and can actually be applied or should be applied at the moment when a company is seriously developing medical devices.

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This means that a company that wants to develop a medical device should try to develop the

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to implement and implement 13485, precisely to generate all the evidence from the development that is necessary.

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A certification body is now finally allowed to audit and certify such a company from the moment suitable evidence is available.

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This means that you decide as a company, you introduce a quality management system according to 13485 in the field of medical devices, you have to live for a certain time.

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As a rule, you have

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a consulting company, like you, which actually helps you to implement the whole thing.

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If you have now decided, I will live this for a certain time, I have enough proof, you can call in a certification body.

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That means that basically it's something different from the MDR.

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We actually recommend starting with certification because, I would say, it has the lower hurdles, because as a certification body, I actually look less at the product and more at the processes behind it.

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This means that I take a very close look at the quality management system and whether it is suitable, for example in the area of development, to produce compliant products.

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This means that it is very process-heavy, although of course the processes always include generating the desired output.

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This means that as a certification body, I can say: „OK, your development process is not suitable, for example in the field of cybersecurity, to generate the evidence required by the state of the art.“

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K., I'll make a short summary.

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That's so much content, Martin.

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A quick breath and whether I understood all this correctly.

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So, we have 2 ultimately legal documents, could maybe say that.

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We suddenly have the M.

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obliges the manufacturers to provide technical documentation, to have a quality management system, to the things that are included in Article 10, for example, and to check whether the requirement of M.

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That is what a notified body also checks.

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And if this review was successful, then the conditions have been created to bring the product to market.

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And besides, I understood you, we have the topic of quality management, also certification.

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So this is not primarily about MDR, but about 13 485, as you said, which is of course also suitable for providing the evidence of the MDR that one is a

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Has a valid quality management system, and you said, and this is now not checked by a notified body, but also by a certification body, i.e. an organization accredited by the DAX, which is in a position or has the approval to issue such certifications.

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And now you've brought something else in.

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That was the time when these organizations are allowed to act.

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I understood you that way, the certification body, it is allowed to become active very early, namely when you actually already provide the first proof.

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Yes, with this focus on processes, then a certification body can be consulted, whereas you said the notified body.

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it should actually only become really active when we already have a product in which we can then take a concrete look.

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Have I understood and summarized that correctly so far?

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That's absolutely right.

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In fact, the notified body takes action with an application that is a formal act.

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The application also includes the transmission of the complete technical documentation.

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That means the product has to be finished, it has to be fixed.

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further development during the application is not possible, but then the product, as stated in the application, must be

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will be checked by the notified body and then it may be placed on the market in this way, exactly.

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This also results in an order, possibly the question to you, so would you recommend that you first strive for a 13 485 certification and then tackle the MDR or do you say, no, we'll do that together in one go?

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In principle, both are possible,

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does not stipulate that the certification must be there beforehand.

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In fact, I don't have to be in one place when I want to use the M.

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which is certified at the same time.

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In fact, I think that's all of them.

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My recommendation is precisely that you first concentrate on certification, because what good is it to me if I have a process that is actually not suitable, for example, to provide certain proofs

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and I go to the notified body.

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Then I have the problem that I submit a non-compliant technical documentation and if that happens several times, it costs me a lot of time, a lot of money and if I have a lot of bad luck and don't manage to generate correct documents in several rounds, the notified body is actually obliged to provide Eudamed, if it ever works, to file a negative report.

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In other words, this is extremely unfavorable for me as an organization.

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When I start the certification process, again,

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I have the opportunity for the auditors to look at my processes and, if necessary, write me a non-conformity that something is missing or not suitable.

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That's not bad for me at all, but a non-conformity is a help for me as an organization that tells me, oh, there's something wrong, I'll correct it and within the framework of the 13485 certification, there are no specifications as to how many laps I am allowed to do.

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That is,

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Quality management system, I won't get a certificate in case of doubt, but I have as many options as I want to correct the whole thing.

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That helps me, because once I have a functioning quality management system, I already know how audit works on the one hand, and on the other hand I know that my system is essentially suitable for generating compliant documents.

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This makes the step into the M.D.R., where I have to transmit exactly these documents, much easier and easier.

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Yes, that's a clear

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Argument, yes, you say that with the 1385 you actually have nothing to lose if you improve or use the advice that comes from the auditors to improve the quality management system to such an extent that it meets the requirements of the standard and thus probably also that of the M.D.R., whereas in the tests as by the notified body, you just talked about the rounds, we have a finite round counter.

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Well, that's a disadvantage and the second thing is that in the worst case it will even be published that you didn't make it.

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but now you can ask the question, hm, if I call you twice now, once in your role as a certification body and then again in your role as a notified body, won't it be much more expensive, so maybe even twice as expensive, because you then have to check twice?

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In fact, the big difference lies in the M.

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yes in the technical documentation, the quality management, if I already have 1, according to 13485 differs only in

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Things that come additionally.

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That's exactly how we calculate it.

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An MDR audit is a static offset to a 13485 audit.

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That means it doesn't cost me more, but it actually doesn't matter whether I do the MDR together with the initial certification, with monitoring 1, monitoring 2, whenever.

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It's always the same sum that comes on top for MDR.

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Of course, I pay a little more over time, because I start with 13485, but that's also a value I have.

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I actually have a certificate in my hand or at least a list of non-conformities that actually helps me.

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That means that in total the whole thing doesn't cost more, if I calculate out the time that I have something in my hands before.

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Mhm, so it's like a step-by-step approach.

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So first you make 13 for 85 and then the delta comes on top, i.e. the small Q.

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This has not been tested in this form in the same quantity before and in total

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it doesn't really matter if I understand it correctly, whether you pay for it in one or 2 batches.

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One is just in one go and the other is 2 steps and you recommend the 2 steps, if I understood you correctly.

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Exactly, because I simply see a great advantage for the organization and it is just 2 smaller plants and not a huge one, it makes it easier for everyone.

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Yes, when we talk about now we talked about money, the second aspect is time.

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What are such typical durations,

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that you recommend or that you observe, from the time a company first approaches you, until you may have the certificate and then again, until you then also have the M.

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conformity.

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You can, of course, depends on the company, but can you give away a rough order of magnitude?

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This is actually quite individual.

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For me, from experience, it's the case that a company that lives a quality management system for a year, so it's introduced, I live for a year,

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has enough evidence to be able to have an audit carried out on site.

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It doesn't help anyone if I go to a company as a certifier, there is a great quality management system in theory, but there is no evidence.

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Then we would actually have to stop the audit, because then we can't see what we want to see.

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This means that a year after introduction is a very good time, when products are often not even ready yet.

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But you can just look at the system and the system proofs and, if necessary, also product proofs, at least the generation of these.

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if it is actually so, ultimately when everything is finished.

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That's often, it's one year out of the first 13,485, sometimes it's 2 years.

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But these are quite productive years.

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These are years when the quality management system is actually improved, where you can say, O.

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K., they are used very, very productively, so that the submission is of higher quality overall.

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And what you also don't, what you also have to take into account, is that if

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If I have a functioning quality management system, I usually submit in the first round, i.e. my first submission, the documents are of much higher quality and I am then much faster in the MDR cycle.

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Because when I get the documents back after the first round with non-conformities, a large part of the time is often with the manufacturer.

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It really takes time to generate documents, correct evidence, whatever.

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This is much faster if I have a functioning quality management system.

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Now we almost come back to the beginning of this podcast episode, namely the topic of M.D.R.

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and their evaluation.

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And one aspect that was always addressed was the availability of the notified body.

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Or one spoke of the bottleneck of the notified bodies.

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Do you still see this measure as we used to have?

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So, does it make sense at all for someone to contact you who is considering getting you certified or getting an attachment certificate?

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Does that make sense at all or are you country under?

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No, we are not underground.

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So, the resources are there, but you have to look at it a bit scope-specific.

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There are areas, such as software in particular, where we really have a large pool of auditors, where we have resources, and there are certainly some scopes where you would have to wait a little longer.

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The big advantage of the approach we discussed before is that once I'm in the 13485, I have booked the notified body almost immediately, because we certainly won't be a manufacturer, we can't let that fall

down, who already has a 13485 with us.

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so he definitely gets a place at the designated place.

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If someone contacts us now and says, I want the M.

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certification, then we can also say that this is technically impossible.

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Perfect, now you just mentioned a keyword, contact you, how can people contact you, what should I put in the show notes, e-mail, a website, what would be your recommendation?

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Well, the easiest way is to actually www.berlinzert.de via our website or, in case of doubt,

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via an e-mail to Zert with C.

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at berlinzert.de, you end up with the appropriate employees.

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This means that the companies that are interested can clarify with you directly what the process would look like exactly, probably also what it would cost, depending on the product and the manufacturer.

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But we learned important things today, namely the big recommendation to bring forward ISO 13 485 certification and if that goes well, then the MDR

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Then you will no longer be added to the role of notified body as a certification body and thus all the prerequisites are created to actually put the products on the market and finally earn money and help the patients.

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Martin, 1000 thanks for these valuable insights directly from a notified body.

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I thought that was something very special.

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Thank you.

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With pleasure, perhaps as a supplement, we offer

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14 daily, always on Fridays, a free M.

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Office hours, where anyone can simply participate without registration, in which such open questions as these can actually be clarified.

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There is no secrecy because it is an open consultation hour, but it is free of charge and everyone can simply participate.

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Every participant who is listening here is of course cordially invited to contact us with questions, even every other Friday.

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Thank you, Martin, valuable hint, thank you, very gladly.

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Thank you for the podcast.

