Class I standalone software?

With Dr. Philip Heimann, Prof. Dr. Christian Johner

Transcript

00:00:05 Speaker 1

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

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After more than 3 years of waiting, or perhaps even more of trepidation, the MDR has now become valid.

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and thus, among other things, a rule 11 has come into force, which directly affects standalone software.

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And of course, this also affects the DiGA manufacturers.

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In today's podcast, I would like to talk to one of these DiGA manufacturers, namely Dr.

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Philipp Heimann and Sven Büttner.

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Could you briefly say something about yourselves so that our listeners know who I'm talking to?

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With pleasure and good morning Christian.

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My name is Philipp Heimann, I am

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Co-founder and CEO of Vivira.

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Vivira is the app on prescription for back, knee and hip pain.

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We have been in the Giga directory of the B since the end of October.

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Farms and for us this is now in the context of the M.

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D.

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R.

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also a very exciting question.

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I am also here with Sven Büttner today and ask you, Sven, to introduce yourself briefly.

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Good morning, Professor Jonah.

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I am Sven Büttner, Head of Quality and Regulatory at Vivira, and as such I am responsible for identifying and complying with all regulatory requirements that apply to us as DiGA manufacturers, as well as our own requirements.

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Yes, I think we have already arrived at the middle of the topic.

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What does this mean now, especially for DiGA manufacturers, if the product no longer falls into class 1 as before, but into class 2 A?

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That is indeed an exciting question.

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We have been discussing this question internally at Vivira since autumn 2019, but also externally with experts: What exactly does this famous Rule 11 mean for us as DiGA manufacturers?

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We are currently a DiGA, a medical device, according to risk class 1,

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And what exactly does this rule 11 imply for us as DiGA manufacturers today?

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The interesting thing for us is that this is still not quite clear, neither to us nor to some of the experts with whom we talk about the topic.

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And this is of course a very central issue, because the DiGA manufacturers who are not yet certified according to Rule 11.

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Of course, we now have to ask ourselves the question, are they the rule, are they risk class 1 or are they risk class 2 A.

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And since not all notified bodies are MDR accredited to date, this may be a question that can have far-reaching consequences for DIGA manufacturers.

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Because if my notified body is not yet MDR accredited, but I am now

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the 2 A.

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certification, it can be a longer critical path on which I find myself.

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So that we and other DIGA manufacturers are therefore asking ourselves this question, what exactly does Rule 11 mean for us today?

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Well, I hear 2 things out of it now.

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The first is the problem that certain things are unclear and the second, even if they were clear, it would be

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can lead to quite a few consequences externally, namely the dependence that you have just described, on the notified body, namely at the moment when a software, a DiGA application is class 2 A, who would you need the notified body and if it is not yet accredited, then this whole thing depends on you.

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I can understand that.

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I think we will have to talk about the topic later, perhaps also internal consequences.

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Absolutely, and that's why we as DiGA manufacturers are now asking you, Christian, and the Johner Institute.

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Yes, when exactly does a DiGA fall into class 2 A according to MDR?

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In which cases is there perhaps a chance to continue as a medical device of reso-class 1?

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Does this possibility now exist or does it no longer exist?

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Yes, the

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Rule 11 has, so to speak, in the last part she talks about everything else.

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Software should still be class 1.

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Now we have to look at the top, so to speak.

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What else is it?

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And interestingly enough, the first branch in Rule 11 is A, which means if the software provides information that is needed for therapeutic and diagnostic decisions or that is necessary for

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serves to make therapeutic and diagnostic decisions.

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This means that if this is not the intended purpose, but if, for example, the product serves directly for therapy, i.e. not for decision-making, but for direct therapy, then this Part A applies.

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and then you are quickly passed on.

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Yes, if you now also ignore these physiological processes, the influence of which can be influenced, then we end up in the last part and then there are indeed still few

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Software that lands in this class 1.

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We ourselves are through our subsidiary, Jona Medical, we have also launched 1 of these products in class 1 under MDR.

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So they exist, this is perhaps the first thing, the good news, but the way Rule 11 is written, it is not much anymore and many notified bodies also find it difficult to construct exactly such cases.

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But now that the MDR is in force, they are actually appearing now and we have

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just examples, such as these products, which directly serve the therapy, which we can then classify.

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Yes, then maybe now back to the point where we were just now.

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You had described or you had described what the external dependencies are.

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What are the

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Meanings for yourself?

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So, what is the big difference for you now, whether you now have a class 1 approval?

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Maybe we can even distinguish 3 things: Class 1 MDD, Class 1 MDR and Class 2 A.

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or higher, also MDR.

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Can you describe from your point of view how the 3 cases differ?

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Absolutely.

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Before

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before I go into the below or before we go into the differences, I would first talk about the equal shares,

because they are quite considerable.

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So no matter whether I allow under MDD 1 or under MDR, the basic building blocks are very, very similar.

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In any case, I need technical documentation, under the MDR it is just described under Appendix 2 and Appendix 3 and I need in any case

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a Q.

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M.

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System, which is at least certifiable according to 13 485, better of course certified.

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First of all, these are the same parts that we see for ourselves.

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Of course, this also means internally that we implement these two big, let's say, projects or large building blocks in our company, i.e. the technical documentation and the Q.

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M.

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system.

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And the

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major differences that we have identified, I'll go through it now in order, so from MDD 1 to MDR 1 as I said, the equal shares are, there are equal shares, the big differences that we have identified from the jump to MDR 1 would be, for example, the requirement for post-market surveillance, then the PRRC, i.e. the people,

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The responsible person according to Article 15 MDR has requirements for labeling UDI and of course the whole issue of Eudamed, which also wants to be dealt with, and that is one part.

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And if you now.

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if we look now, from MDR 1 to MDR 2A is the big difference, as we said at the beginning, that's why these external dependencies, that I have to have a notified body look over it in any case via the technical documentation and that I have to get an O.

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K.

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I need the product to be okay and that's the main difference or differences that we see in the different

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classes or the various differences.

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We just talked about it, now what the influences of classification are and yes, it was points like the person Responsible for Regulatory Compliance.

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We have about U.

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D.

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I.

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We talked about the topic of integration at one point.

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But these are all things that don't directly affect development, implementation, are they?

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No, not them, you're absolutely right, Professor Jonah.

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So the development process is

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Basically, it's the same at first.

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I have to comply with 13 485, 62 304 and other regulations or standards.

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The big difference between MDR 1 and MDR 2A is the involvement of the notified body in the review of the technical documentation.

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And depending on whether the notified body with which you work as a manufacturer is already accredited or not,

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it is the critical path that we talked about earlier.

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So normally it takes a certain amount of time to initiate and go through this process.

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But the main difference is that with MDR 2 A.

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I absolutely need a notified body to check my technical documentation and for O.

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K.

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so that I can go into the registration with it.

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Actually, it's good news.

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That is, if a manufacturer now switches from 1 to 2 A.

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and he has cleaned everything up, as is required of the basic requirements of safety and performance requirements, and if he has documented, as Annexes 2 and 3 now also require, it makes no difference at all.

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So I think a point that you just mentioned, yes, of course, we have the notified body, which can push things back again

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and what you sometimes see in practice is that yes, because someone looks at it again, then perhaps a little more detail is worked on.

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But the classification does not play a role in terms of regulatory requirements.

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Exactly, and that's where I would like to start briefly.

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We welcome this in this sense and if our notified body would be able to give us MDR 2 A.

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to certify,

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Then that would be exactly the case, because we at Vivira made a trend-setting decision some time ago that we do not see regulatory as a necessary evil, but as a key enabler for growth as a medical device manufacturer.

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And that's why it's important for us above all to have clarity.

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Well, what are we now?

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It's not our decision whether we are 1 or 2 A.

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And then it is also very important that a corresponding notified body is then also available.

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Exactly, perhaps there is the question to you, Professor Jonah, as we have now talked a lot about the implication of MDD 1, MDR 1, MDR 2A and a lot stands and falls with this notorious Rule 11 the classification rule for software and there

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I would be interested or would be interested in how do you see the current wording regarding this regarding the classification of software, medical production software, is the A.

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sensible and B.

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is it well formulated in this form?

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Yes, I think I had already announced in other channels that I had a stomachache in some places

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and I don't think even the EU will claim that Rule 11 is somehow the showpiece of the M.D.R.

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What bothers me about it is that it is not a risk-based classification.

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If you look at this, especially section A, you will notice that this is only about degrees of severity.

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But the idea, it is also called risk classification, is that probabilities and degrees of severity are really also considered, because in the most unlikely case we always have very serious damage

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And then the software would almost always be sorted into a much too high class and that makes no sense in my opinion.

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And I think that also makes sense of the E.U.

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Commission does not really make sense, because that is exactly why they have created this M.D.C.G.

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document 2019/11.

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And if you look at what is in there now, you have to come to the result, yes, that actually contradicts what is written in Rule 11.

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It weakens them significantly.

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And what happened there, that at the very back, I would almost like to say, almost a bit lovelessly, an I.M.D.R.F.

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classification.

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And this classification is now going back in the direction of risk.

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Yes, all of a sudden, the patient's condition and the directness of the influence on the device, on the therapy and on the treatment play a role again.

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This means that we are moving back towards risk-based.

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I think that's very good at first.

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What I don't like is that there is a lack of clarity about it now.

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Yes, what applies now?

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Do I do rule 11 now or do I go in the direction of M.D.C.G.

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2019 11, which would actually make sense.

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There are now just a few notified bodies, say yes, what is in the law, that is the law and we stick to it and it leads to these far too high classes.

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So first criticism, they have not corrected the error in the law, but have tried it somewhat unlovingly with the M.D.C.G.

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Document

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The second thing that we, which I don't find quite optimal, is that we have in this M.D.C.G.

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Paper then also a few derivations or statements where you would have to question again, for example that they say, yes, if the thing does nothing more than store information, forward it or expose it to a simple search, then it is not even a medical device.

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And I find that a bit strange now, because

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functionality is described here, otherwise it is always claimed that it is the purpose that decides and not the functionality.

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And in my opinion, that creates a certain chaos again.

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And the third point is that even with the MDCG MDCG paper, i.e. including the IMDF classification, we still have no way to go back to class 1.

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That was also intended to a certain extent, but you have to think about whether it is really risk-based, because we really have products where very banal therapeutic decisions are made and then you end up in class 2 A without anything worse happening now.

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And I think you need a little more guidance, a little more experience, maybe even later spoken law to get this clarity.

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which you rightly admonish.

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Yes, those would be my thoughts on it.

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I think we have gained a good overview of what the classification means, on the one hand for the DiGA manufacturers, but I also think for all other manufacturers of standalone software.

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We differentiated, once again MDD versus MDR, MDR class 1 A versus the higher classes and at the end we even went into it again, yes, how should this actually go on now.

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Yes, thank you very much, Philipp.

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Thank you very much, Mr. Büttner.

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Very, very gladly.

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Thank you very much.

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Yes, then see you next time.

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Thank you for listening.