

Unjustified regulatory requirements?

With Sven Wittorf, Prof. Dr. Christian Johner

Transcript

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

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The complaints to the MDR are becoming more and more severe.

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And so the EU Commission has sent to the FITEN

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said that it was not only her fault, but that subsequent institutions would also additionally and unnecessarily tighten these requirements.

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And because we heard this more and more, we wanted to find out if this is really the case.

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And for this reason, we have launched a survey together with Medical Mountains that addresses exactly this topic.

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So the main question was, is there

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are there actually demands that are made in our ecosystem that are not at all justified by the MDR itself?

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And our regulatory scientist, Sven Wittdorf, played a decisive role in the evaluation.

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He did that, working on other data, which we would also like to present in another podcast.

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But this one is now about this survey together with Medical Mountains.

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And we would now like to give you a very brief overview of what came out of it.

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So,

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Who did we ask at all or what did we ask these people?

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So we actually asked everyone who wanted to say something about it.

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So these are manufacturers, these are also notified bodies, which of course also face demands from authorities, for example.

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And everyone answered in the end.

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Of course, mainly a large number of manufacturers, but also notified bodies have given feedback, authorities have given feedback, test laboratories have given feedback.

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Even private individuals who were on the road as auditors had the urge to give us feedback.

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What were the questions that we had in this survey?

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So we had four questions.

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The first question was, what demands do you see yourself exposed to, which you consider unfounded, from notified bodies, authorities, whoever, in this overall system?

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Then, how was this demand justified, by the other party?

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Why do you think this is unfounded and what

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Does it have an impact on you if you meet this demand?

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In fact, the only binding question we asked was the first: What demands do you face?

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But almost all of them answered all the questions, also with a lot of heart and soul.

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That perhaps as such a basic feedback, because it was pure text questions, could be read out very well.

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There is really pain, there is frustration, but there is still a lot of passion and a lot of will to contribute.

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We received very, very valuable feedback, from which you could tell that someone had

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took a lot of time to enter that.

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It was a three-digit number, if I remember correctly, who took the trouble to fill it out extensively.

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Yes, we had over 150 total responses with a total of over 100, i.e. almost 180 individual demands.

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So sometimes two or three were written in one.

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We pulled them apart, there were 178 very precise demands.

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Okay, now you've done the work of reading all of this.

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Because we had deliberately decided not to make Likert scales or any drop-down lists, but to give the possibility to answer in free text.

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You did the work of censoring it all and then finally categorizing it afterwards.

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Who was the most criticized and maybe what was this criticism?

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So the main criticism was or most of the feedback was on notified bodies, the behaviour of notified bodies.

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also on the subject of MDR itself, i.e. demands of the MDR that are not considered sensible or not justified or too high.

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That was more like that in the area of complaints.

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So we asked for demands, what demands are you facing?

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And about two-thirds of the feedback was also concrete demands, where in the end, I think, you could also evaluate a result, i.e. a true or false, so to speak.

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And then you have about a third, which was, I'll say, rather general complaints, so in the direction of everything far too much effort and a lot

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for small products, we have products that have been on the market for many, many, many years and now suddenly the product is no longer safe and stuff like that.

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And what was also a very interesting result was that there was a lot of rubbing and a lot of discussion and also uncertainty in the direction of MDCG documents.

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And on the one hand in terms of content, they tighten things up a bit, is that right, but also, I'll call it administrative.

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So how binding are they actually?

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And then manufacturers see each other

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Demands that all of them must be met, all of them must be put on the list of standards and there was a great deal of uncertainty and are they actually allowed to do that?

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Are they allowed to demand this, because they are guidance documents and they should not actually be binding.

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Now you have already mentioned the first examples.

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So maybe first of all, there is a lot of criticism of notified bodies, their demand, their behavior, if I understood you correctly, then of number two, the MDCG documents, which have unleashed a lot of criticism.

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Could you maybe

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perhaps give an example for both, i.e. where it was now a matter of very concrete demands that were suspected to be unjustified.

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So there was something like the requirement that you have to submit the complete file for a reprocessible Class 1 product.

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Also things where one has frowned a bit oneself that there are demands that a notified body must now be involved for class 1 products, the notified body claims.

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because in the regulations for, so this was already at the special corners, for dealers and importers the term „notified body“ is somewhere.

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So much, much criticism of small-scale interpretation, also a lot, what actually needs to be included in a declaration of conformity?

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And then there is in the MDCG document what makes more demands than the MDR and then

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Then the notified body says, then you have to take the MTCG document, mandatory or your own templates, I've also seen that several times, that just notified bodies probably out of the motivation to help, have their own templates for, how to structure a file, which forms do you have to fill out.

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And that always ensures that there is simply multiple work for the manufacturers and also a lot of frustration.

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So what you said now, I criticize the

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is to tighten demands that have no basis in the MDR at all.

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I think you hinted a bit earlier, there is also criticism as far as behavior, dealing, communication is concerned.

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Can you perhaps give some examples?

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Those were the four highlights, i.e. a lot of simple processes, most of the points of criticism were very much, as I said, MDCG documents, a lot of uncertainty and so on.

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Also almost on the same level the topic, I once called it communication and collaboration, i.e. interaction to

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a lot of actually notified bodies at the point, so because simply, it takes too long, there is no uniformity, it is, for example, very concrete invoices are issued before the service is provided and processes are changed on the part of the notified body, which has ensured that you had to resubmit the file three times, just then correspondingly process-compliant.

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They were demands for the consequences of a trial, which was not communicated at all.

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Those were things like that, so a lot, a lot of frustration, a lot, but simply, it takes too long.

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Why don't I get any feedback?

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Need a very long time of feedback.

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The notified body always points the finger at the ZLG.

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So the reason is quite often, the ZLG wants it that way.

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And then, of course, there's a killer argument, let's call it.

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And in the end there was a lot of frustration.

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That was also the starting point of this survey, namely complaints about the ZLG and I had met the head of the ZLG and he said, let's know what they always claim, the notified bodies, where we, the ZLG, are to

blame.

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Then we can take a stand.

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And that's exactly what has now been initiated.

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So to make that concrete now.

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And are now the

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Things also came out in this survey where the notified bodies say that the ZLG is the bad guy.

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So at least they do.

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So the manufacturers do that and refer to it.

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The notified body says it would otherwise get into trouble with the ZLG.

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The notified body says that the ZLG requires the

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And that's where it got stuck.

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Then they either agreed or not.

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Much is still floating.

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So for many months now, it has not gone any further.

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And whether that is the case, we want to find out exactly now.

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There was also a lot of positive news in the survey or in all the trappings and what you said.

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The ZRG wants to know for itself, so we are now playing it back to the ZRG as well.

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I think we owe that to all manufacturers, who have made a lot of effort to write very openly where it pinches and very precisely.

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And we have just filtered out the feedback, from which we also hope for clarification from the corresponding, I'll call it institutions, which are criticized.

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That means we have a list for the EU Commission, we have a list for the Ministry of Health and TRIP BfArM including and we have a list for the ZLG.

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The list from the ZLG is the longest.

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These are almost 70 very concrete points where we ask the ZLG to take a position.

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That means that the wish of the ZLG has been very much heard.

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It is precisely these concrete points that will probably be frightening now, because of the amount that is coming their way.

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But I believe that once we have clarified this, then there will simply be more clarity in the system again and that in turn will help everyone.

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Yes, you have already answered the question to some extent about what will happen next.

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So I understood you to be the

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Results are clustered.

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The results are also divided or the requests are divided among the respective recipients.

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EU Commission, BMG/BfArM and ZLG/Notified Bodies.

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That means that this is now going to everyone.

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Then we hope for feedback from there and then the next step will be that we then communicate this feedback back into the system in order to then communicate it back into the system with

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more clarity, to make it a little easier to survive in this crazy system.

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What are your next steps, Sven?

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What else is coming up for you?

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Yes, my next steps are to wait for feedback to come.

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Perhaps in addition to what you said, we do not come here as supplicants with a list and say „Hear us“, but we have been actively asked.

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I think you've already said it in at least a subordinate clause, but I also think

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This is one of the most important things that triggered the survey.

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There is an interest in those who are criticised really entering into dialogue.

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And my steps are to help push this dialogue, i.e. also to accompany the communication in the direction of the ZRG, in the direction of the BMG and to be ready there if there are any questions along the way.

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So the ideal thing would be, two hours after we sent it, this list comes back filled out.

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We don't count on that, but I don't think it will be delayed.

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The interest of everyone is there to help.

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And my step is to have an ear on it and keep an eye on it and then evaluate it accordingly and communicate it back in the same way.

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Some and many of them, I would say, of the participants, have also left us very specific contact details.

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What else we are planning, however, is not yet quite sure whether everyone will go along with it, that we will then also pour it into a consolidated document.

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and then have them more as best practice or as collected answers.

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FAQ maybe.

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That's how it was in the direction of FAQs.

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And this will then again be distributed via their channels with Medical Mountains, which were part of the survey.

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I may perhaps mention that you are still working on a second research project.

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Would you like to say a word at the end of this podcast about what data you are currently tackling and maybe like this

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one or one and a half highlights.

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Yes, although I think the highlights at this point are rather lowlight.

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So we want to understand the system, we want to improve the system, we want to be able to make predictions about what will happen if regulatory conditions change.

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And we are still at the very beginning with the question, yes, what is actually going on in the system?

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And there is very, very little data actually.

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And we just saw one source, these are surveys, which are of course always a bit biased and then they say, if you

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then there is scolding.

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But the data that are actually the most reliable and the most secure are the registration data for medical devices, which are unfortunately still spread out in Europe, in the individual countries or member states.

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And what I have done is that I have all the reports that are made in Germany, in the German medical device database and information system, which used to run at DIMDI now at BfArM, where all product,

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Ads and revocations and change notices and finally all the incident reports, although I didn't look at them, converge.

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And what I have done is to evaluate how the registration and revocations of medical devices have changed over the last 30 years, so this database starts in the nineties with the MDD, how they have changed so much, what trends there are, what impacts there have been,

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at the time MDR.

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And a lot of things came out of it that I didn't expect at all and that are also very frightening.

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So the lowlight is that we see that German manufacturers, so we have the German database, that is, we know the registration of all products from German manufacturers and the registration of the products of non-EU manufacturers who have their authorized representative in Germany.

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And then the relationship has turned massively, so to speak.

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So ten years ago, 80% of all products from German manufacturers were still placed on the market.

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And now we are still at just over 30 percent.

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And what you can also see is the legal basis under which the products that are on the market are current, and you can see that just 20 percent of all products have just been converted to the MDR.

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And this after two years that the MDR no longer exists.

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This means that 80 percent of all products on the market are current, I'll call it dead.

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So you can only do life-sustaining measures at most, but significant changes in the sense of innovation are not possible.

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And

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I think that worries us a lot, because it means that if you project it into the future, the manufacturers will only revise files in the next few years and not create innovations.

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And the first evaluation showed that we cannot afford that, because we are simply continuously losing market share.

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We now as German industry.

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So we have to talk about it a little longer, but I think we'll do that.

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Yes, there is another podcast about it.

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These are really disastrous results for those who are partly responsible for this.

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We also presented the figures to the EU and the other stakeholders at the World Medical Device Summit.

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I was in Brussels, I also showed them again to the responsible departments that take care of medical devices.

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The consternation was great, but of course that is not enough to solve the problem.

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And so we will continue to do everything we can to achieve this.

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in one direction, because they change the regulation, so that products come back onto the market, so that we can have innovation again, so that our location here does not completely hit the wall.

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Some participants have already spoken of deindustrialization, which we are observing here.

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And we will do everything we can to achieve this.

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And of course, we will now try to make our contribution not only at the legal level through data, through information, but also by helping to make a difference in this system with

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better to survive.

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An approach in which we then also take out all these processes of digital transformation, with which we then also take out bottlenecks and let all these communication difficulties, which you also described earlier, be a thing of the past.

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Yes Sven, so you can say that we really have a problem and we have now quantified it very clearly with all these studies that we have done.

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So there's no excuse here anymore, it's not so bad.

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It is really bad and we would like to thank all those who have helped to create this clarity, which is the prerequisite for improvement, very, very much for the work they have done and thus also made a contribution to improving this system.

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And of course, a huge mega thank you goes to you, Sven, who is doing this endless work of fighting his way through hundreds of data sets, classifying, processing and now putting it all into a form,

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that you can ideally answer in binary afterwards, the demand is justified or unjustified.

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So thank you very much, Sven.

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There you go.

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Thank you too.

