

The Corporate Will of Medical Device Manufacturers

With Prof. Dr. Boris Handorn, Prof. Dr. Christian Johner

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Transcript

00:00:00 Speaker 1

And it says exactly what documents I have to keep about the termination of business activities.

00:00:07 Speaker 2

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

00:00:17 Speaker 2

Recently, a public authority asked a manufacturer how he would ensure that even in the event of insolvency, the customers of this manufacturer, this medical device manufacturer, would continue to

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could have access to the documents.

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In the end, this authority also expected a kind of company will, and we have already reported on this in the Institutional and received a lot of feedback.

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And then it was also asked what legal bases would be based on this.

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In other words, whether the authority ultimately has the right to demand this at all.

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And so I thought, this is a good opportunity to call in an expert and so today I have Professor Boris Handorn.

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here in the podcast, with which we want to discuss exactly this topic of company wills, regulatory principles, but also how something like this is implemented.

00:01:07 Speaker 2

Mr. Handorn, you are very welcome.

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If you were to start, how does one actually become a lawyer?

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Perhaps also someone who later dealt with company wills, like you, what prompted the young man to take this path at that time?

00:01:24 Speaker 1

I greet you, Mr. Jona.

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I

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yes, I'm not a specialist lawyer for company wills, there's actually no such thing in that sense, but how did I get started?

00:01:36 Speaker 1

I am actually, I come from this pathological and sometimes lethal area, to stay in this medical image.

00:01:46 Speaker 1

That means I started with product liability and international product liability and then, of course, this one.

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have had all kinds of cases on the table where it is said that it would have been good if certain things had been documented 5 or 10 years ago or if they still had this documentation.

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So that also means this experience from this in contentious lawsuits, what is the effect of what I am doing today and that is ultimately also something that we have to anticipate in the company will,

00:02:23 Speaker 1

what do I have to think about in the future and in principle this product liability area, which was initially quite broad and then it went relatively quickly, that I specialized in the field of medical device law and pharmaceutical law and also covered all this regulation.

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So, it was a multi-stage approach as they continued to specialize.

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First lawyer, then product liability and then product liability for medical devices, pharmaceuticals and of course we are now getting into our domain in more detail.

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Yes, also with the medical device requirements, including these company wills.

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Could you give us a first list of laws that have something to do with this

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will, just get an overview of this whole area before we dive into the individual requirements in the next step.

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I had also read your institute journal and was actually a bit surprised about the term company will in fact, because it is not a legal term, but it also describes quite well that you should also think about the future and what will happen after me and

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is also a legal entity of G.

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M.

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B.

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H.

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an A.

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G., then, in case of doubt, also an afterlife that has to be organized.

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So that means conceptually there is no such thing, but what is it all about in the end?

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I have to think about what risks can threaten in the future, be it for the company itself or if the company no longer exists, please also for patients and users of my medical device.

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especially in the medical device sector, you have a very high responsibility there.

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A few years ago, there were reports of highly innovative implants provided by start-ups.

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Early movers among the patients have had this implanted and the companies have disappeared from the market.

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And what happens then, there is no more supply, no replacement products, possibly no replacement products with which I can then reimplant myself.

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So also

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that when I do something, when I put products on the market, I take on a responsibility.

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Legally, civilly, by the way, one also speaks of traffic safety obligations.

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Yes, and they should be taken seriously.

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You can also well imagine, now you have something like that implanted and now maybe some post-market information comes back and now you are faced with very big decisions, for example, how do I have to recall the product, does it have to be there, does it have to

00:05:02 Speaker 2

What other measures do I have to take and then logically the recourse to a risk management file or to construction drawings, for example, is very helpful in order to be able to make such decisions.

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So I think you can understand it well in terms of content.

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Correct, i.e. ideally, it is actually the case that within the framework of such a company will or even a product will, the

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the actual information about how a product works, what the risk looks like, and whether it is still available, regardless of whether I have voluntarily made the decision to leave the market or whether it has actually become a company insolvency.

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So that means, we can summarize at this point that the authority does this, it doesn't have anyhow, that sounds reasonable, yes, so there, that's not some kind of statistical impulse, but there is an ethical one

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Reason, so since the issue of patient safety is the trigger.

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But that doesn't mean that there is a legal reason, of course there is.

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That's why we come back very briefly to the question, which pieces of law should manufacturers of medical devices have in mind now, in particular, if they want to find out what is actually required in this contextual company will?

00:06:19 Speaker 1

Yes, listen to us today

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focus on the regulatory medical device legal requirements.

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There may be corporate law requirements, tax law requirements and so on.

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Within the framework of this format, let's stay with the question of what it looks like in the broadest sense with my technical documentation, with my product file and in fact, that is regulated by regulation.

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Take a look at paragraph 5 Medical devices

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Law implementing law, i.e. our M.

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P.

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D.

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G., the national one, there are actually regulated retention of documents in the event of cessation of business activity.

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Yes, and on the one hand it is about the storage of certain documents by manufacturers or please also note if I do not have an E.

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U.

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manufacturer through authorised representatives.

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And what should not be overlooked, there is also a paragraph

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2, which also obliges sponsors or their legal representatives based in Germany in the context of clinical trials to retain certain documents even after the cessation of business activities.

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The whole thing is not just a pure national requirement, what is often overlooked is that it is actually in the M.

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D.

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R.

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but relatively far back, i.e. in the facilities.

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so paragraph 5 then again refers to the annexes of M.

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D.

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R.

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for example, Annex 9 in the context of the conformity assessment procedure Section 7 under the somewhat dry heading Administrative provision, yes that is already misleading, as it is written there.

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However, these are requirements for the manufacturer, not only for the administrative authorities, and it is exactly there that it says which documents I will also have to use as part of my conformity assessment.

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on the cessation of business activities.

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And in the usual periods that we have in Article 10 (8) MDR, namely 10 or 15 years for implants.

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And then the MDR legislator and you, dear member states, say that you please oblige your companies in your states to comply with this.

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And that's exactly what Paragraph 5 MPDG says.

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This means that if an authority

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If you look closely at it during an inspection, then of course it makes practical sense to say, why do we need your documents at some point, but the simplest answer is that it's in the law and that's why they demand it, because that's exactly how it's regulated.

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Perhaps a small note on the question, what does an authority do with it once it has been made available, that is possibly problematic.

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So the idea behind it is quite good.

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The only problem is, their regional council around the corner or the BfArM, what do they do with a risk

management file, with technical documentation overall, they don't have the capacity to replicate the product or to give it to someone else in any way, please rebuild it or service it to you.

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That is, the purely practical question, what does an authority do with it,

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This may actually be problematic.

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But the basic idea that you say you have this information, especially the risk information, is completely correct and regulated by law.

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Mhm, the good news is, as you have described, we have a relatively clear top-down legal approach, namely from M.

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D.

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R.

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down to the M.P.D.G., where all this is explicitly stated that these documents are to be kept.

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I think we will come back to the question of practical implementation very later, also because you have now also raised the question of what the authority does with this data.

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But the good news is, there are places where you can read exactly what we have to do here now.

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Let's go into this requirement in detail very briefly, i.e. what is in it, what is now required by the manufacturer exactly,

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before we will surf on to this other area.

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Right, exactly.

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In terms of structure, let's stay with the manufacturer or the authorized representative.

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When it comes to the storage of conformity assessment documents, such as those listed in the annexes to the M.

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D.

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R.

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are regulated.

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So there are references to Annex 9, Annex 10 and Annex 11 in the case of custom-made products, by the way, also reference to Annex 13

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there is a detailed list of which of these documents are not all, but which must then be kept after the end of the activity.

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We already have retention obligations, yes, the 10 and 15 year deadlines in Article 10 (8) MDR for all manufacturers.

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This means that the regulatory requirement applies according to the system for those manufacturers, again very roughly speaking, class 2A and higher.

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which subsequently carry out a corresponding conformity assessment procedure in accordance with Annex 9.

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Purely formally, pure Class 1 manufacturers would be practically out of this overarching retention obligation, i.e. beyond the death of the company.

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Nevertheless, it still makes sense to comply with this even with class 1 products with a lower risk.

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Can we give the manufacturers a kind of rule of thumb.

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So you can say you have to ensure complete technical documentation or access to it.

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And now the question, also certain Q.

00:12:16 Speaker 2

M.

00:12:16 Speaker 2

Documents, so because they have just mentioned Annex 9.

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Exactly, let's stay with the example, Appendix 9, the whole thing is basically terrible to read.

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This is paragraph 5 reference to Annex 9 Chapter 3 Section 7

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if we go into it under these well-known administrative provisions, there is again a list of which documents I need from Annex 9.

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One is the E.

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U.

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Declaration of Conformity, well is also done relatively quickly, then the documentation mentioned in section 2.1 and section 2.2.

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Yes,

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and then the information on the change in accordance with section 2.4, the documentation in accordance with section 4.2 and the decision reports of the notified body.

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And within the framework of these references, you may understand that for yourself and then scroll over, but the reference is then again implicit, if you then go to section 4.2.

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These are the application documents that show the design, manufacture and performance of the product

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and these include the technical documentation in accordance with Annexes 2 and 3 of the M.

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D.

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R.

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That is, to answer your question, we actually come to the point where the complete technical documentation has to be deposited in the event of the termination of the business activity.

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You have just mentioned subsections of Annex 9.

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What would you have to do with Q.

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M.

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Documents

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?

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So, you have already answered part of the question, namely, for example, the part of the Q.

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M.

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Documents that are necessary for the application.

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And.

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If I remember correctly, I think it's things like the most important procedural instructions that are already included.

00:14:04 Speaker 2

So, you could perhaps also say that the Q.

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M.

00:14:05 Speaker 2

Manual.

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Do you see any other mandatory parts from the quality management system that would also have to be ensured?

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So in the end, the

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all the documents necessary for the application for the evaluation of the complete quality management system.

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No, as a reference to 2.1 Ultimately, the documentation, which then also allows the quality management system to be understood and evaluated in the first place.

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Mhm.

00:14:36 Speaker 2

So the summary is, dear manufacturers, complete technical documentation including conformity assessment, complete quality management system, including application, that's that,

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which must be provided by law, even if you have passed away.

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Exactly.

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Yes, when we talk about dying, we should also talk about life.

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As you have already indicated, companies will not only die now because they almost go bankrupt, for

example.

00:15:05 Speaker 2

There are other constellations, it could be, for example, that it is simply sold and then the obligation of this provision goes

00:15:12 Speaker 2

Position to the buyer or does it remain with the original company, what else would manufacturers have to consider overall?

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Yes, you have to pay a little attention to how such a transition takes place in terms of company law.

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There are the nice terms share deal and asset deal.

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That is, if I say I'm making a share deal, I'm selling a legal entity as such, a G.

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M.

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B.

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H., then wanders

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everything that is part of the G.

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M.

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B.

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H.

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including these regulatory obligations, will then become the new shareholder.

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That's a relatively manageable constellation.

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The term asset deal means that individual pieces are bought out and sold, that can be machines, they can be patents, but that is also the documentation, if another company now decides, I'm not going to buy G.

00:16:07 Speaker 1

M.

00:16:07 Speaker 1

B.

00:16:07 Speaker 1

H.,

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but there's a nice product group in there, I'd like to have it and use it for myself.

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Then it is the case that this must of course be regulated and can be regulated, how should the product documents continue to be handled.

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But what you have to keep in mind, the G.

00:16:28 Speaker 1

M.

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B.

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H.

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as a legal entity still exists and you should definitely make sure that you then also settle with the acquirer,

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where is the risk demarcation, where is the regulatory risk demarcation.

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In this case, you can also control that.

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To give a practical example, they say, what is it sometimes good for thinking about the termination of a business model, do I still have the technical documentation.

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The liability risks for product defects, which may then arise after the sale, usually remain with the

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Sellers, so we'll stick to this asset deal again.

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I'm a G.

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M.

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B.

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H., I sold an entire business unit.

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I may not even invest in medical products in the future.

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But what I have placed on the market continues to bear liability risks.

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As a rule, I make a distinction between seller and buyer, dear seller, what you have done so far, these risks remain with you.

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And here is a short excursion into civil law, i.e. product liability law.

00:17:39 Speaker 1

There, under the current legal situation, you have a risk for product liability regardless of fault from placing the respective product on the market for 10 years, depending on fault, this can take even much longer.

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And what we are now

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, but is still being implemented, that the so-called Product Liability Directive is based on E.

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U.

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level, the so-called P.

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L.

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D.

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is a directive that must be implemented at national level by December 2026.

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So, there will be a new product liability law in Germany and there will still be 10 years of liability risk, but there will also be the risk of up to 25 years for so-called latency damage.

00:18:24 Speaker 1

This means damage that may only typically become medically apparent after 12 to 18 years, and there the legislator will regulate in the future that, for example, cytotoxic risks, even cancer that can develop, only exist over very long periods of time, that there are liability risks of up to 25 years.

00:18:45 Speaker 1

And now a second one is being added and that brings us back to the question, see to it that you document for the future.

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In the future, there will be so-called disclosure obligations for evidence.

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This means that in a product liability lawsuit, a plaintiff can demand that the defendant disclose conformity documents.

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And if we go back to the regulatory area, these are ultimately exactly these conformity documents, technical documentation, with which I have to prove in case of doubt that I

00:19:19 Speaker 1

I have complied with the regulatory requirements for my product many, many years before that, at a time when I may not really know my product anymore.

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And if I can't do that, if I can't present this documentation, then a so-called facilitation of proof applies.

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This means that it is assumed that the product did not comply with the regulatory requirements, nor, and this is important from a liability point of view, that the product was not free of defects.

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Yes, then I can still try to prove that there was no error, but that will be very difficult.

00:19:56 Speaker 2

That means, now I have to summarize very briefly, because now I'm slowly having Stack Overflow.

00:20:00 Speaker 2

So we started with the question of what happens if the company is sold.

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We ourselves wanted this very sad case that the company went bankrupt, so it disappeared from the market, we wanted to hide it and see what would happen if the company was sold.

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And then they have

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let us know.

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We first have to distinguish how it was sold.

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So is it really complete, so to speak, i.e. that the shares or company shares have been completely transferred to someone new or have only certain parts of this company, for example a product division, been transferred?

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For example, the company has resold all its medical products with what goes with it.

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In the latter case, I understood it that way, it depends on what the two companies

00:20:45 Speaker 2

i.e. to whom this responsibility is subsequently transferred to provide these documents.

00:20:52 Speaker 2

Whereas in the event that we have a complete sale of the company, i.e. the company or shares have been transferred to someone new, so to speak, I'm not quite sure yet, I understood it correctly, then the liability also passes to this new buyer to the buyer.

00:21:09 Speaker 1

Liability for

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in fact, and also the regulatory obligations, which remain with this company, which is sold as a whole, stick to it, then nothing changes there for the time being.

00:21:22 Speaker 2

O.

00:21:23 Speaker 2

K., so that gives us clarity now.

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Yes, so that, so her answer was, it simply depends on the form of the sale, whether these disclosure obligations, if you want to call it that, are transferred or stick to the old one.

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But then they opened the door to a new room and said, in addition to all these medical device legal things, we now also have the new liability issue.

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So they have already announced that we have a new directive that will be transposed into national law, and this liability will result in comparable or almost identical obligations, namely for disclosure, because without this disclosure the manufacturer would be put in an unfavourable evidentiary situation.

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That's how I understood her.

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In fact,

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Indeed.

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In other words, we have to consider several pieces of legislation, even from very different areas of law, when we talk about the disclosure or provision of documents, especially technical documentation.

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Now we have spent a lot of time talking about these regulatory frameworks, and now perhaps also about practical implementation.

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So the company is now making its will, but what is it writing in there now?

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So to put it another way, to whom should I hand it over in the worst case?

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So you give it to the trustee, because you have already indicated that it may not necessarily be in the right hands with the authority and it is probably not the duty of the authority to become the archivist of the entire medical device industry.

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They would thank you, they would thank you.

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That was probably the small revenge of the manufacturers.

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by simply flooding the authorities with their files.

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But is probably not what the authorities want, possibly not what helps patients.

00:23:07 Speaker 2

What would be your recommendation, what are typical instruments, approaches, partners that you can use to keep your documents available even in the event of death?

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In this context, in any case, first of all, the hint, if you then also look at the 5 MPDG, there is also

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an authorization to issue ordinances to the Federal Ministry of Health, which says, dear B.

00:23:34 Speaker 1

M.

00:23:34 Speaker 1

G., you can make regulations on how this is to be implemented, for example to designate a place where such documents are to be stored or, interestingly, to oblige the manufacturers and authorized representatives and sponsors in the area of application of this law to create central offices.

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Such an ordinance on

00:23:58 Speaker 1

There is no such thing at the national level, so it doesn't mean they don't have to do it, but they have a relatively large amount of leeway to do the whole thing risk-based and appropriately for their product portfolio.

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And you can also live out a bit by saying, yes, which can be stored in the form of electronic storage media, which are then readable for the entire duration of the retention period.

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That would be something that the

00:24:27 Speaker 1

but you can also read that electronic documentation is also possible without further ado, but I would also have to worry about whether someone will be able to read a floppy disk at all in 12 years.

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So if we go back 20 years now, it may have been the case then, but today it is rather doubtful.

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Yes, so that means that this would be part of the yes of quality assurance and quality assurance

00:24:56 Speaker 1

and the rational one, which I have to deposit for myself, that I say I store physically, I store electronically and, in case of doubt, electronically, in which formats do I do this in order to be future-proof.

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I may then no longer exist, especially in the event of the complete liquidation of G.

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M.

00:25:15 Speaker 1

B.

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H.

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and this is also the same under company law with other documents that may then have to be filed,

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then I can also choose, with whom I deposit it, is it a notary, is it a law firm, is it any other body, but which I then instruct in the event of my liquidation, if an authority comes, then it is deposited with you.

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In practice, it may also be advisable to inform your own competent authority about it when you leave the market, because I also have to log out of the system, not only

00:25:54 Speaker 1

if I am a manufacturer.

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And in the process, if I ask the authorities anyway, the information has to be transferred as well.

00:26:03 Speaker 1

You won't get the documents, but I'll tell you where the documents are.

00:26:08 Speaker 1

And you can also coordinate this with the authority at an early stage, if you don't have a sudden death right now, to say, how can this be handled in an orderly manner, whether the authority

00:26:21 Speaker 1

agrees to this.

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However, they have relatively large leeway in terms of form and place of deposit.

00:26:29 Speaker 2

Yes, that was precisely the form and place, I think those were also the big keywords in your answer.

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Maybe let's start with the place, what I've learned, we should actually almost distinguish whether we have a sudden death or not.

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So, can I still communicate with my authority at all, if I can, we had a relatively long time, namely until the unfortunate moment.

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then to inform where the authority can find the documents.

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But if you want to anticipate this sudden death or want to cover this unfortunate one, then you do indeed need this will, where it is actually regulated.

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And you have considered notaries, lawyers, perhaps other people or institutions of trust as a place, for example.

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Do you do something like that?

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Because that is what we, what we do for clients, also as persons subject to professional secrecy.

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O.

00:27:18 Speaker 2

K.,

00:27:18 Speaker 2

So, that means it would be a way to deposit that there as well.

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So, that was the question of the place that you have just mentioned, and the information about the place, which the authority must also know later.

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And you pointed out again and this is also a legal requirement that we not only list products in the database, but now in the German case of the B.

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F.

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A.

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but also have to deregister.

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Yes, we know from our own research that there are major deficits.

00:27:43 Speaker 2

So, there are many products that have not been deregistered, but.

00:27:47 Speaker 2

That's just part of it.

00:27:49 Speaker 2

And the second complex that you opened up was the question of what form.

00:27:54 Speaker 2

And you said that legibility via the maps, if necessary, is an important, important aspect.

00:28:00 Speaker 2

And this in turn now has various sub-aspects, namely the form of the medium.

00:28:06 Speaker 2

So, you said, a CD will probably soon be unreadable or by most.

00:28:10 Speaker 2

And then we have the level of formats.

00:28:13 Speaker 2

So, there are certain file formats that don't know, no.

00:28:17 Speaker 2

Lotus 123 file, I think, as it used to be called, will now no longer be able to read most people and there has established itself, among other things, either PDF A as an archive standard for documents or, for example, XML for structured data.

00:28:32 Speaker 2

So that's what we've covered as well.

00:28:34 Speaker 2

Yes, we have already been to the question of how can you help now.

00:28:38 Speaker 2

You said that as a law firm you can also

00:28:43 Speaker 2

yes, serve as a kind of executor or as a depository.

00:28:47 Speaker 2

How do you help companies in this context of the will or perhaps also the question of how can people

contact you?

00:28:54 Speaker 1

I prefer to help proactively.

00:28:56 Speaker 1

That means that the requirement here is that you wait exactly for this case.

00:28:59 Speaker 1

This is also the regulatory requirement.

00:29:01 Speaker 1

In other words, the question of how it can be structured in individual cases, what else do I have to consider, how do I link this in my quality management system, please also think about Article 10 A.

00:29:11 Speaker 1

M.

00:29:11 Speaker 1

D.

00:29:11 Speaker 1

R.

00:29:11 Speaker 1

this is also a precaution for the question, I cancel products for whatever reason, you can also combine that.

00:29:19 Speaker 1

And so to speak, this legal rationale that is behind it, how can I organize this, how can I do it in such a way that I, as the management, do not have to be accused of organizational fault.

00:29:32 Speaker 1

Of course, this is part of our usual proactive advice that we offer for companies.

00:29:38 Speaker 1

That is absolutely clear.

00:29:39 Speaker 2

I would say your

00:29:41 Speaker 2

email address or their website.

00:29:43 Speaker 2

So that means that all those who need legal support and we have just learned it, just not, not only when drafting company wills, they should turn to them with confidence.

00:29:53 Speaker 2

Yes, Mr. Hanton, it was a great interview, actually a sad topic, to talk about wills, but I still think it was a very entertaining one and the two of us, your company, my company, make sure that this case does not occur at all if possible.

00:30:06 Speaker 2

So in that sense, thank you again a thousand times for this interview.

00:30:09 Speaker 1

Thank you, as always, a great pleasure.

00:30:11 Speaker 1

Thank you very much.