Johner Institute

What the EU AI Act means for medical device manufacturers

With Dr. Till Klein, Prof. Dr. Christian Johner

Transcript

00:00:05 Speaker 1

Medical Device Insights is a podcast from the IONE Institute for medical device manufacturers, authorities and notified bodies.

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Especially in the case of medical devices that use artificial intelligence processes, the question is often asked: And who is liable if the AI has done something wrong?

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But this question of liability is not limited to medical devices with AI, but it actually affects all products and medical devices as well, of course.

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And so in today's podcast we would like to shed light on what kind of laws are there regarding liability?

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Who is liable?

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What do you have to pay attention to?

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How do you proceed if there has been some kind of trouble?

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And for such

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legal issues, we also need a real lawyer and we have a Daniel Handorn.

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And Mr. Handorn, can you briefly introduce yourself so that our listeners get to know you, so that you know what you are already doing in this context?

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Yes, wonderful good day from my side.

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Thank you very much for the invitation that I can be there.

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I myself am a lawyer and have been doing product liability for 17 years, so I originally come from this pathological corner, to these cases where something went wrong, i.e. this

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a few percent that may go wrong, but which can then also really hurt.

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And based on my experience, I later specialized in medical devices and life sciences, where I combine regulation with liability issues.

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I myself am a lawyer at the product law firm, there at the Augsburg office and as a partner responsible for the life sciences sector.

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So exactly our man medical devices and liability exactly what we want to talk about today.

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Let's start, maybe this sounds like a layman's question to you, but what is regulated there anyway?

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Where is this regulated?

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And you also said in the preliminary conversation that something is happening or has something just happened?

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Can you give us, as a layman, an initial overview of the regulatory level at which we are moving, which laws, ordinances and guidelines we should keep an eye on?

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Yes, in principle, the following applies to medical devices

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as for any other product, i.e. for toys, for machines, for automobiles.

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This means that the MDR or the IVDR do not essentially regulate liability.

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Reference is made to the European and national systems.

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In concrete terms, this means that core product liability is regulated in accordance with the European Product Liability Directive,

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which has been implemented in all European member states, which would be the Product Liability Act in Germany, for example.

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This means that there is no specific medical device liability, in contrast to pharmaceuticals, by the way, which in Germany are subject to their own strict liability in the Medicines Act, although it must also be said that with the MDR one or the other liability implication has come in.

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So if you take a look at Article 10, there is something like a compulsory cover provision

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for product liability exposure, product liability risks of companies.

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It is regulated, the liability of the authorized representative, that he should be liable in the same way as the manufacturer and a few other topics where you simply notice that the MDR wants to bring together liability and regulation much more.

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That's the principle.

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This is product liability.

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That's strict liability, that's

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Strict liability.

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There, no one asks about fault.

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It's just a matter of whether a product is defective?

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And then there is always a national fault regulation in the national product liability or liability systems in general.

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In Germany, this would be the so-called tortious act, tort law, which is in principle to liability for fault.

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If I harm someone through my behavior, I have to be liable for it if it happened illegally and culpably.

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Where

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In the area of the so-called producer liability, fault is also presumed in the end and I as a producer, as a manufacturer, must prove that I am not at fault for the damage or that I am not at fault.

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was not at fault for the breach of duty.

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It takes place within this framework, which means that we always have a European legal situation that is implemented nationally and a national legal situation, and that comes together cumulatively.

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Now you have already indicated that there are changes in this area.

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What should manufacturers keep an eye on?

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Product liability law.

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I am currently living in very exciting times.

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The drafts for a new product liability directive at European level are now available.

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It is important to know that the product liability directive that was previously in force dates back to 1985 and that the need to adapt the product liability rules to digitalisation has now been seen above all.

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So AI, software in 1985, the software that existed at that time, at best you still handed it over on a floppy disk.

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So now there are questions such as AI, possibly also self-learning in the field, how am I liable for this?

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How is it to be put on the market, how is it to be designed?

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And what is the relevant time for liability?

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And the regulations that are now being considered, however, will also affect completely different, i.e. also analogue products.

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It's not just about

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to sharpen AI liability, but the trend is always towards more consumer protection.

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And perhaps we can still get to that.

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There will be a few critical points that are still under discussion, some of which will also be criticized relatively strongly at association level, for example, when it comes to reversing the burden of proof for complex, innovative, especially medical devices, which could then be faced by manufacturers.

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Okay, I'll summarize very briefly so that you can check if I understood it correctly.

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So we are currently in a situation, we still have a European directive, as we know it from the old medical device days, it needs a national law, in this case the Product Liability Act.

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There are a few others, but that's the central pillar on which it all rests now.

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But now it goes on.

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Now a regulation or directive is to be introduced at the European level, now I have to ask a brief?

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The directive is to remain, in fact, which must

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must also be implemented again.

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Okay, that means that then we would have a directive, which means we have to adapt the law again and now, of course, the exciting question is, what will change there and you have already indicated, in general, consumer protection should be further strengthened and at the same time and associated with it, modern technologies should also be used and you have now even explicitly mentioned AI, are thus taken into account and

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there, in order to become even more concrete, it is then also about topics such as reversal of the burden of proof.

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So that means that we are probably heading for a tightening from the manufacturer‘s point of view.

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Right.

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On the other hand, in the essential points, one can say that the concept of product is affected.

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So far, it has been controversial whether software is a product at all, namely a movable thing.

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In the future, it will be made clear that software is also a product in the sense of product liability law, i.e. a concept that we are familiar with in the medical device sector anyway.

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It will be exciting for the field of 3D printing, for example, that digital construction documents, so-called Digital Manufacturing Files, are also covered by it, i.e. in distinction to the service, to a development service.

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If I make such files available, develop them in which

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the future product is depicted, then it is also a product within the meaning of product liability law.

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This means that the developer is liable for this digital construction document.

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The second major point will be the concept of error, which will be much more closely based on regulatory violations.

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So here, too, regulation and liability come together much more closely.

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What we have to be prepared for is a disclosure of evidence.

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will come with legal certainty.

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In the medical device sector, we already have the possibility of facilitating access to conformity documents for potential plaintiffs.

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This will be generally extended to the entire product liability landscape and regulated in more detail.

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The purpose of the whole thing is to create a level playing field, i.e. information asymmetries between the manufacturer and the

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and consumers.

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However, this also means that with the documentation, which may be relevant to liability, you become much more transparent towards potential plaintiffs.

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This can also be from collective actions, it can possibly also be health insurance companies, which then demand access to their documentation in order to simply see what went wrong.

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Wow, these are already massive changes that are pending.

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Do you have an estimate of when

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this new Directive could be adopted.

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The draft directives are currently in the legislative process at the European level.

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The planning is that we will have the guideline at the end of 2023 or the beginning of 2024, so not long at all, and according to current planning, the

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Implementation period at national level 24 months.

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That means that if we then extrapolate it, we will have a new legal situation, at the end of 25, beginning of 26.

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Okay, so that means we still have a little time.

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On the other hand, it's good to prepare for it and, even in the worst case, to stand up to your documents, although I think the MDR has already encouraged us enough to do that.

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Nevertheless, it must be done.

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You know how fast it goes,

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the transitional periods in the implementation of the MDR, time passes very quickly.

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Yes, the years are flying.

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These are some relativistic effects, I think.

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You have actually already said that there is no distinction in the field of medical devices and non-medical devices.

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Are there still things that medical device manufacturers should pay particular attention to?

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So that medical devices have been relatively much in focus in recent years, especially the

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product liability law dogmatics.

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So many of the leading decisions at the European level, including those of the Federal Court of Justice, i.e. the German Federal Court of Justice, came from the medical device sector.

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That was a relatively big, big trigger.

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Points are also taken up with the new legal situation.

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For example, this topic of abstract probability of failure as an error.

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So in the area

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active implantable product.

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This was developed there by the ECJ.

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The whole thing is now being transposed into the then applicable legal situation in the new directive.

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This means

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In the end, medical devices are a special substance, simply with a greater risk profile, because we are doing something to people and the exposure to liability per se is greater.

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Okay, so I understood you that way.

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You say that while there is no difference in the specific regulation or requirement, the specifics of medical devices in particular have been factored into this general regulation.

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Right.

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And if you take a look at the drafts, the current recitals mention, for example, medical devices, high-risk medical devices or innovative medical devices such as medical AI as particularly complex products, for which there may even be something like a facilitation of proof in the future, i.e. that the damage comes at the level of error and at the level of causality

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of this potential error, the manufacturer comes much more into the burden of proof and the burden of proof, my product was not defective or my product did not cause this damage.

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So in the case of particularly complex products, and in the case of medical devices, as it looks like, we are very quickly in the burden of proof according to the legislator, the burden of proof can be much greater.

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Okay, now we've been talking about product liability for quite some time.

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Now we should perhaps dive into the question of who is liable at all.

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It can be that the company, the top management is often heard, the individual.

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You also talked about it earlier, maybe the developer.

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Can you break this down a bit, i.e. how the evaluators are taken into recourse?

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Here, too, as a lawyer, you have to distinguish between the individual so-called bases of claims.

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That is, in product liability, which we have just talked about, i.e. in the

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Core, this strict liability, where the company, namely the manufacturer or the manufacturer of a supplier component, possibly the importer, is liable.

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But this ultimately affects the company.

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The individual can be liable himself under the law of tort.

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So that would be paragraph 823 paragraph 1 of the German Civil Code in Germany, because

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because it says that anyone who harms another and does so illegally and culpably is liable for the damage.

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This means that this can also affect the individual employee.

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And basically on every level, where you have done something wrong.

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Now it has to be said that in the external relationship, i.e. towards patients, towards health insurance companies, the civil law, the liability claim of the individual employee does not play a major role in practice,

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Because in the end, the manufacturer is the focus of such lawsuits.

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Internally, things can look different.

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So whereby the individual employee then in turn has certain privileges under labor law at the level of fault, when it comes to top management, management, organs, there may also be organizational negligence in the internal relationship, i.e. also in relation to the company, in internal recourse in the end.

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And what does play a role in practice if I have done something wrong, and that ultimately leads to safety-relevant non-conformity and damage, is criminal law exposure.

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In essence, we are not talking about civil liability.

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It is a criminal liability.

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However, this can affect any individual, because the company itself is not criminally liable.

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That's always the one who has something

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or refrains from doing something that he should have done.

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So I summarize, so under criminal law it can affect the individual.

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I think that's what we've now seen in this emissions scandal, where individual people have also been dragged in front of the card, for criminal reasons.

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Today in the podcast we talk about product liability and they say that the company is clearly in the foreground as a possible target of an indictment, not so much the individual, but

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However, in individual cases, of course, employees can be taken into recourse, although there is usually not much to be gained and practice shows that it is not so particularly relevant, which of course is not a call for sloppiness.

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What do you recommend to companies, executives, individuals to be absolutely sure or to increase the probability that there will be no problems, that they will not be held liable, that is, that we

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three or four best practices that you wanted to pass on to our listeners.

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From all the experience, I think the primary tip is that a clean documentation that you can then refer to, in five or six or seven years, if anything happens, is the best insurance that you can also understand, yes, we thought of something in the way we did it.

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That was our solution.

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And you can

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Consistently explain how you developed, how you produced, how you also carried out product monitoring.

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Because if you don‘t have such consistent documentation, you‘ve often already lost because you can‘t prove that we did everything right.

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Therefore, it must also be said that in the field of medical devices, if you look at the quality requirements and requirements for technical documentation and how do I develop, if you take it seriously,

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you are already very much on the safe side, because we are a highly regulated industry.

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And in the future, too, it will become increasingly important to be able to prove that you have done your regulatory homework in order to be prepared for the event that someone comes.

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I have been harmed by your product.

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This means that we finally have an advantage as a medical device manufacturer.

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We've been condemned to documentation all along.

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And that helps us now, so maybe there won't be quite as much on top.

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Of course, we have just seen that we still have issues in the area of AI and medical devices, but these are also areas where regulation and also case law are only developing and some things are now being anticipated by the new directive.

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This means that the call on manufacturers, especially in these areas, even if not everything has yet been regulated in detail, to simply achieve this traceability and

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I think that with our AI guide, for example, there is already a lot of what you should do.

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Finally, perhaps one more question: What do you do if it happened anyway?

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So I think anyone and everyone can sue.

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What do you recommend as a lawyer right now?

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How should you react now when you receive such a letter?

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What is the escalation or how can it be de-escalated?

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What are the

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Steps that you should take in order not to make things even more difficult for yourself somewhere.

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Well, it is perhaps more of a preliminary stage, there is often an incident in the market, some findings from product observation and then you are already faced with the question, do I have to react with a field measure?

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We have the regulatory requirements, but also the liability requirements, because within the framework

of producer liability they also have product monitoring and

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Hazard avoidance obligations and then it goes relatively quickly.

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So that would be the first practical tip.

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Basically, they rarely have the time to process a regulatory clean recall and then take care of possible recourse issues with component suppliers, for example.

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Because you have to think about it, you also have examination and complaint obligations to be fulfilled immediately and the deadlines are relatively short.

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That means you have to talk to each other in the company and have to see, do we possibly have to secure recourse?

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Certainly also the question, how are we insured?

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You have the obligation to provide minimum coverage that covers your liability risk.

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But how, for example, is your supplier insured?

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This is also something that you can look at in the context of contract negotiations, in the context of annual audits.

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So basically, it goes relatively quickly and the tip is certainly also,

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that you have an appropriate setup for such crisis-like situations in the company beforehand, a committee that then meets, which then makes sure that you don't think about it when such letters come.

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When it comes to the question of whether a lawsuit comes in, well, if it is already in court, then you can't get past the lawyer at all.

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If it's at the district court, much more often claims are now pre-litigated, out-of-court, i.e. you will be contacted, something happened here, please pay.

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Then it depends a bit on the setup of the individual company, but at the latest then it becomes legal and then it should get legal help, be it internally in the company or through external lawyers.

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So you are welcome to advertise yourself now, too, so when should people come to you?

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So we have just learned that if such a letter flutters into the house, of course, then we need legal assistance internally or externally, so we are lawyers at the front.

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Are there things where you say you can help in advance?

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It's actually a big part of our job to proactively sort things out in such a way that you already have these risks under control.

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Yes, and in fact not to prepare at all with a view to product liability, but simply with a view to quality assurance, to safe products.

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That something can slip through, that someone complains, even if there is nothing to it.

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in the lawsuit, even then it is possible to sue.

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At that moment, you are already there, prepared, possibly already know the company quite well and can then actually help very efficiently with knowledge of the processes and the products.

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You order and then also talk to the lawyer on the other side.

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Okay, so we learned a lot today.

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So we dived into the question, where is all this regulated, what is changing?

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And I think that's right now, as we've learned, for medical device manufacturers

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innovative products, what is to be done with them is particularly relevant.

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We have investigated who is liable, when the company is liable, when the individual is liable, in the context of product liability and criminal law differences.

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They gave us tips on what to do, i.e. preventively, to avoid it.

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So before something happened, so to speak, but they also said what to do if

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which is indicated when there is something on the bus and when the child has finally fallen into the well, i.e. when a lawsuit comes in, at the latest then you need help.

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You are one of the people or the law firms who can provide help.

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And that's why we will simply add your contact details to the show notes.

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Yes, thank you very much, Mr. Handorn, for being there and I hope that all our listeners have learned a lot.

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Well, I definitely have.

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Thank you very much for that.

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Thank you very much.