Johner Institute

Placing on the market: a concept that needs to be understood

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

Transcript

00:00:05 Speaker 1

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

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There was recently an event on the subject of A.I.

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in medicine and a few ethical topics were also discussed and the

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thesis that had quite unsettled many researchers.

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And this thesis was that if researchers, especially now in the university context and in the medical context, use algorithms, A.I.

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develop algorithms and then post them on GitHub, then this is a placing on the market of a medical device, at least if these algorithms can be used to diagnose or treat.

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And if that's the case, then

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the researchers will of course have a big problem, because they will not have the means and infrastructures to act as manufacturers, and that would then cause the whole research to falter.

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They do that, as you can guess, researchers, researchers in general, to publish, because that's their business and with it they get new research funds and with it they just want to advance science.

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And now we have to clarify this, do we now have a placing on the market here and that is now a very le-

gal question and that‘s why I decided to

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again and that is the lawyer Handern, who briefly introduces himself so that we all know him.

00:01:34 Speaker 2

Yes, wonderful good day to the round.

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Boris Handern, my name.

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I am a lawyer and partner of the product law firm there at the Augsburg office and we only deal with products, with non-food and I myself specialize in the field of life sciences and there very deep in the field of MDR.

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So, we have a medical device expert with us here and of course also an expert on the topic of placing on the market, and we are now going directly with another.

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What is placing on the market and why is it relevant that we really define this term precisely and hopefully understand it just as precisely in a uniform way?

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Well, as a lawyer, I say that the term should be used precisely simply because it is legally defined.

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Because the MDR gives a definition of placing on the market and you shouldn‘t invent any new terms so that everyone knows what you‘re talking about.

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Just as a clear distribution of roles between economic actors is important.

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But why is placing on the market so important?

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There‘s just a lot to it.

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It is practically the central axis of traffic with medical devices.

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They must have registered the products themselves as an economic operator before placing them on the market.

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When placed on the market, the requirements of the MDR must be met.

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Certain documentation and retention periods begin and, last but not least, product liability is linked to the placing on the market, namely at the time of placing on the market, the product must meet the justified safety expectations.

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So exactly this time is insanely important and

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last but not least, we are still in the transitional phase of the MDR, which has now been stretched out again.

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That is exactly the point, are you still allowed to place a product on the market or not, within what transitional periods?

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So the big appearance, am I still marketable or am I not?

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K., so the definition, I'll just read aloud now and then we'll hook in a bit.

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So the MDR says that placing on the market is the first time that a product is made available on the Union market, with the exception of investigational products.

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So, now of course the first question is: What is the product?

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Is that a product type?

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Is this a product instance?

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Yes, and what is for the first time?

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Can we perhaps dive into it very briefly to see what the legislator has come up with?

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So, it is very important to note that the term „placing on the market“ refers to the respective piece, to the respective thing, i.e. not to a product series.

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This means that it always depends on when I hand in the respective piece.

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And the term „placing on the market“ was always the first place on the market, even in MPG times.

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The first making available of a product on the market refers to another definition, namely that of making it available on the market.

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Again, this means any supply of a product, whether in return for payment or free of charge, again with the exception of test devices, for distribution, consumption or use on the Union market.

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And this in the context of a commercial activity.

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That is, these two definitions must always be seen together and any further provision in the market is what the trader does.

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And putting it on the market for the first time is what the manufacturer or importer of a non-EU product does.

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K., that's very, very helpful.

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I think we will talk about the importers in a moment.

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Now you have once again brought in a, I think, important word or pointed out that it is in the definition.

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That was this, the concept of the commercial.

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I think that's a very important aspect for our researchers, if I see it correctly, because the assumption I

have of researchers is that they don't pursue a commercial purpose.

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Is it already permissible at this point to say that this was not a provision because there is no commercial background?

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That would be

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a criterion that would make me raise my eyebrows and say that this cannot be the case here.

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The second point here from my point of view would be that it is not a matter of discontinuing or dispensing a medical device in case of doubt, because it still depends on the subjective purpose of the potential manufacturer of the product.

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And if I upload software purely for research purposes and that's clear, then it's not a medical device either.

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K., I think many stones will fall from the hearts of researchers at this point.

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That's great now.

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Now you have just emphasized a second term, namely this one for the first time.

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Yes, and can we perhaps dive into it a bit?

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So, at what point is a product then placed on the market and is the advertising of this product, if it has perhaps not yet really come onto the market, already such a placing on the market.

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So maybe a thought where this could also play a role, especially in agile development.

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there are more such small experiments that you say, OK, I'm planning a product, for example, you call testing demand.

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And they just claim that I have it.

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Yes, and of course it plays a role how this is to be sorted legally.

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So perhaps that as a background to the question, i.e. at what point in time is the product placed on the market and, for example, does advertising already count as such?

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So in principle, you always have to look closely at each individual case, what you are doing, what activity you are doing with regard to the medical device.

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But in principle, the magic word here is the delivery of a product.

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So that's the definition we have in the market when it comes to deployment.

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And placing on the market is the first provision, i.e. the first supply of a product.

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For me, there is always a very good supervisory authority, which is also what the Blue Guide 2022 says in general for European product law.

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This is when a product leaves the manufacturing phase and enters the supply chain

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enters the supply chain.

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So that's always a step back and say, is that what I'm doing right now?

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Especially when it comes to applying.

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In principle, you have to assume that advertising is not enough for you to put it on the market, because simply this act of handing over a product is not yet fulfilled here in my view.

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The submission basically has something actual or I have a legal transfer.

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the domination of property, the power of disposal over a product.

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So something has to happen outside of the application.

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But there is another regulation that is perhaps not so well known or so much in focus, if you take a look at Article 6 MDR.

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So, for example, if you offer a product online, if you offer software online, then the product must meet the requirements of the MDR at the time you offer it.

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Offer then also includes the advertising for this product.

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In other words, the market surveillance authorities also want that in principle.

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It's like a provision fiction.

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I only offer something online, but the product must then be compliant, because then a consumer or the professional circles could buy the product at any time.

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And

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the market surveillance authorities then already have access to it.

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So a distinction has to be made, we have the situation that the advertising, the offer, triggers the conformity of the product.

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But it is not a placing on the market.

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Prerequisite product exists at all, yes, as if someone just says I have something, but it doesn't exist at all.

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That's right, that's also a good test point, because they often advertise products that may not even have been produced.

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And we said earlier that placing on the market always refers to a specific product, if it has not yet been produced, it does not yet exist.

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So, we are diving deeper and closer and you have already really let another point swing between the lines, namely does this now also have something to do with these ownership and ownership relationships?

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You have already said that this could perhaps play a role.

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Can you say something else?

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Yes.

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So the term „placing on the market" is defined under European law.

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Yes, it is to be interpreted in the sense of the MDR or in the sense of product liability law.

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The terms property and possession are terms that apply in Germany, they apply according to the Civil Code, so they are defined there, are civil law categories.

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They are directly related.

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To go into the terms specifically, the concept of property is in principle irrelevant for placing on the market.

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For example, if you sell a product to a retailer and you have agreed on a so-called retention of title, then this has long since been put on the market.

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yes, and at the dealer, but you, colloquially speaking, still own the product as a security right.

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So that alone shows that ownership doesn't matter.

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Nor does the definition of possession actually not, although here the factual interfaces are very large, because possession is actually more based on actual control of property, just like the concept of levy,

which also refers to a

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transfer of actual control of the property.

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In other words, we are not talking about the transfer of possession here, but the actual intersections between the transfer of possession and the placing on the market are quite large.

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K., I'll summarize very briefly.

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So, what used to be important, we are talking about every single product when it comes to placing it on the market.

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yes, not from the product instance.

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Also in M.D.R.

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Terms would be if it is now a non-software, every single U.D.I.P.I. that leaves the thing with us, that's a single product, that's what we're talking about.

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First time means that this individual product is handed in for the first time.

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Perhaps as a demarcation, if I understand correctly, it would be a second time, if someone then simply resells it.

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Yes, I may have sold it to a dealer and the dealer sells it to a hospital.

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Then this second step would not be the first.

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Yes, that means that the marketing is then more or less from the manufacturer, in this case to the dealer.

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That's what is meant by first time and not, I have a product type for the first time, so to speak, what I call a C.T.

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of type X.Y.

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for the first time, but we refer to the individual.

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Then we had another discussion about how it is now related to property and possession.

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So first of all, these are completely new concepts.

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We have to distinguish between national law and European law.

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We have to take care of European law here, because that defines the concept of placing on the market.

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The German definitions of property and possession are not entirely relevant here.

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Ownership doesn't fit at all anyway.

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It would be most comparable to this with these ownership structures.

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But as I understand it, we should simply rely on this European law

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Supports and in this context we had also looked again, when does this delivery take place?

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And they said that an important indication is whether it has already been entered into the supply chain, as they had formulated it.

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And what they also pointed out again was the special case of software.

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where you said that the moment I make this product available on my website and thus also advertise it at the same time, someone could then work directly and then there is also a marketing.

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So, that's my understanding, did I understand you correctly?

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On the last point, I may correct you, we do not yet have a place on the market, but we have an offer and for the offer since Article 6 MDR, at the time of the offer, you must already be compliant, then the authority can also

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require an EU declaration of conformity, because then you basically open your shop and then you can download or order at any time.

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But that is not placing on the market.

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This means that placing the software on the market, for example, would then actually be the moment when someone downloads it.

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Oh, thank you for making that so clear, because with that you have already answered the next question again, which I just wanted to ask, namely the difference between software and not software, and so this moment of the

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Downloads, so as you just said, then the decisive one.

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Great, so precision is important.

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Thanks for correcting.

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We had already teased another case earlier, namely the case of importing products.

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When is the import of products placed on the market?

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Here we have the situation that the manufacturer is not located in the Union and the placing on the market is the first provision on the Union market.

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This means that the importer has a central role to play here.

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So the importer is just like the manufacturer the distributor.

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And to make this concrete, in the case of imported products, it is usually assumed that the product is placed on the market at the moment when the product is released for free circulation under customs law.

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That's the moment when customs opens the barrier and says, yes, that

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Product is compliant and you may continue to distribute it.

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So in this respect quite interesting, already at the moment when the importer gets it released, which is a duty-free warehouse, and the importer stores it at his place, a placing on the market has already happened.

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This means that it is not necessary for the importer to hand over to a dealer.

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This is not so precise from the definitions, but it is simply for the purpose that at the time when customs says, yes, the product is allowed into the Union, the product is then also

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is already subject to the supervision of the market surveillance authorities, even if it is still with the importer.

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This is the rule.

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However, there are exceptions, and in my view you have to look carefully in any case, for example if you have a situation where the non-EU manufacturer hands over the product to the importer for inward processing.

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The importer must first make it marketable, for example he gives it a German instruction manual.

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and labels it and adds its own importer label.

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At that time, we have a different customs procedure, then the product is already de facto in the Union, but the placing on the market has not yet taken place.

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So you can see that on the one hand we have an actual concept, on the other hand it is a legal concept that must also be underpinned accordingly legally.

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But the principle is release for free circulation, which is a pretty good yardstick.

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Great.

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if we are talking about international or non-European manufacturers right now, what would that look like in the case of software products?

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So the a U.S.

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manufacturers, for example, on the Internet and also offers companies to or hospitals, patients, whoever, in the European area.

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How would you assess that?

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There is often the exciting question, do I have to order an importer for my products?

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And that's not the case.

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Non-EU manufacturers must appoint an authorised representative, who is then the contact partner of the market surveillance authorities, but I do not appoint an importer.

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The import is also something factual.

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So someone who does something that an importer does is then the importer, and there can be a lot of that.

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But there is also something like direct import, direct acceptance, and even a hospital that then downloads software, for example, is not an importer, but a health facility.

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That is,

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conceptually, no importer has to stand in between in the supply chain.

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So, what's happening here?

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We have again said, Article 6 in the, I offer this, that is, I have to be compliant, even if this software is still outside the Union on some servers and of course at the time of delivery, in the end it is the first distribution in the Union, but this then takes place directly between the non-EU manufacturer, he is also the distributor,

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and the health facility.

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So here, too, the system works, no, and even this online offer is subject to market surveillance, although at that time a placing on the market, as we said earlier, has not yet taken place.

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Oh, great, thank you for this clarity, I'm happy about that, because that's the precision we always need and, as you say, it depends on the individual case, but you've just described these individual cases or examples of them to us, and that's not just one thing

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In general, it depends, and afterwards you are not any wiser.

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So, I'm definitely much, much smarter than at the beginning of our conversation.

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Maybe let's get to the end, already so slowly.

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What should manufacturers pay attention to in this context?

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What are perhaps also mistakes that you often observe or that then perhaps lead to problems, which in the worst case even hit you?

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What do you give them?

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Yes, so if you don't have these clear cases where really a product physically ends up from one to the ot-

her,

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There, caution is always advised as to whether you have a situation here where you can already assume that it will be placed on the market, because there are also legal transfer concepts, so to speak.

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For example, I can transfer a product without it physically moving out of a warehouse.

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So I can also transfer a stock to the external storage service provider, was a legal act.

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That means you no longer own for me, but for my dealer and that is a placing on the market.

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It is even possible that discarded goods, but which

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must be precisely determined, is in stock with me and I store for the dealer.

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Only they notice that these are legal concepts, I have to underpin this contractually and I have to make it clear which goods are involved, so that caution is always advised here, because the consequences are immense.

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Yes, so if I have a marketing even though the products are not yet compliant, that has bad consequences,

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the same is true of the case, where I think I have placed the goods on the market and have not done so, just think of the transitional periods of the MDR, because then you can dispose of the goods if you have torn a transitional period by doing so, and it has not been placed on the market, even if through a legal concept, you can also throw the goods away again.

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So from that point of view, this is very important, if you do not have clear cases, please always look at the individual case and you can also be on the road in a legal way.

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So please ask.

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Yes, so then in exactly those cases I would say that you are called upon.

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We also link your contact details again so that this clarity can be created, especially in all these special cases.

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Let's conclude very briefly, perhaps with our researchers.

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What would you recommend to them so that they can continue researching in peace, publish, and post their code on GitHub without having to worry that something is coming up legally?

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So, what are maybe

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News or downs that you would give them.

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So in the case you have described, I am already thinking of the question of the intended purpose.

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In other words, what does my software do, what is my software for?

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Is this possibly even a test product?

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Yes, is the intended purpose something that I am conducting a clinical trial here with a view to a later medical device?

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So that means that in this case, from my point of view, it does not depend so much on the question of placing the product on the market, as it was said earlier,

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it's not commercial what they do, but also the question, please be aware of it, if you set something like this, then really for research purposes, because if you say that you can also diagnose wonderfully with it, then it's a medical device or then it's an I.V.D.

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and then we have a completely different problem.

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Mhm, so a corresponding disclaimer could probably help where it is simply clarified again that the

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what is in the ReadMe in GitHub, that would be, so to speak, that is often the entry point in this repository, if you simply say, hey, this is not a medical device, but an algorithm, this is the result of our research

and should please be understood as such.

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Exactly, always be completely clear that this is research and is not suitable for medical or diagnostic purposes from your point of view.

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Great, yes, and in all other cases, if there is any ambiguity, I link your contact details,

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so that everyone can approach you directly.

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Well, I really learned a lot in today's interview.

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I am very, very grateful to you.

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And yes, all that remains for me to do is to wish you a wonderful day and thank you again for being with us.

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Thank you very much for the invitation.