

Impact of the Ecodesign Directive on medical devices and IVDs

With Dr. Harald Oehlmann, Prof. Dr. Christian Johner

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Transcript

00:00:00 Speaker 1

My conclusion is that we should wait and see at the moment.

00:00:03 Speaker 2

Yes, definitely.

00:00:04 Speaker 2

So, the Ecodesign Regulation is a meta-regulation.

00:00:10 Speaker 2

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

00:00:20 Speaker 1

Today's podcast episode will be a relevant one for pretty much all medical device manufacturers.

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I'll tell you why in a moment.

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It's very difficult for regulatory affairs professionals to get into all these details that you should dig into.

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On the one hand, this is because the further you go into the topic, the more ramified it becomes.

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I'll give you an example, we have the topic M.D.R., from there we continue in the direction of Oidamit, from there we continue in the direction of U.D.I., from there it goes in the direction of perhaps barcodes, from there we continue in the direction of G.S.

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One and then maybe verifier and then again detailed standards.

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And it is very difficult to be familiar with all these ramifications.

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Now there's a second complexity.

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Of course, this is always the case when orthogonal regulation is added, i.e. like an A.I.

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Act, such as PFAS or the Ecodesign Directive.

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And today I brought in someone who is perfectly familiar with these ramifications, especially when it comes to this topic U.D.I.

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goes.

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He is also active in the M.D.C.G.

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on this topic and that is Doctor Harald.

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Oelmann.

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Mr. Oelmann, how did you actually get involved in this area?

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How did you get involved in this U.D.I.

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topic in love and what are you doing in this whole context?

00:01:36 Speaker 2

Yes, so first of all, thank you for letting me be here today.

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Thank you very much, Mr. Jonah.

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Yes, it was when I was 16.

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So my father had a barcode company and at that time I invented barcode symbologies.

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That was Coda Block F.

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as a student

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And that was ready for operation in 1988 with my high school diploma.

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And from 1992 onwards, the dental industry in particular was deeply in love with this code and started and massively promoted standardized barcodes at that time.

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And today you would say, yes, I've been doing U.D.I. since 92.

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That is, that's how you really know it.

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Can you describe very briefly how you got into this, into this M.D.C.G.

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Community?

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That's not a banality either.

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And what are you doing in this context?

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Yes, that, that was actually quite a sliding.

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So first of all, the dental industry, the one of Fide, wanted to get me there.

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However, this was rejected because of possible

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Multiple interests of my person, because I am active in many areas.

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So I was already involved in medicines before and then I'm very active in standardisation, so I'm the project manager for Datamatrix, for example, and then standardisation was looking for someone to join this committee and so I could hardly defend myself there.

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So this

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You were really, really catapulted into it and the Commission is also very much involved in harmonised standards, is very active.

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And the man for harmonized standards, Mario, is now also for U.D.I.

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So at the beginning of the year, the Commission rotated again.

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They do that every 3 years, so that people basically change around it.

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And I had already made good friends with Mario at that time and I had already discussed today's topic, namely D.P.P., in the commission and so it now came across to the committee, so to speak.

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Yes, after you didn't want to have them at first, you really wanted to have them, because you realized that it doesn't work without specialist knowledge and of course they have it like no other.

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So I don't think anyone is looking at a

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3040 years of career in the U.D.I.

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area.

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I think there are few who have immersed themselves in the norms in this area as much as you are, and that's why I'm super happy that you're with us.

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You have already mentioned the keyword D.P.P., so we should clarify very briefly what it is and where it comes from from a regulatory point of view.

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So, what has changed in terms of regulation and what has it to do with D.P.P.

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or what is D.P.P.?

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Yes, D.P.P.

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Digital Product Passport is called Digital Product Passport and this has been an initiative for a long time.

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In the beginning it was called digital twin, so you try to get for every object that exists, typical it would be, for example, if I had an iPhone now and I buy it and there is a code on it and when I scan the code, I now get exactly the information for

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my iPhone.

00:05:01 Speaker 2

That is, it says when it is manufactured, what can the thing do exactly, what is installed in it.

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But what is also particularly important, how can I possibly recycle it, how can I dispose of it, this information is also included.

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So not only user information, but the entire circular economy information is contained there.

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And that's where it comes from here, namely ecodesign, regulation, I think, or

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the Ecodesign Regulation, which requires exactly this Digital Product Passport and yes, digital passport, yes, you have to find it somewhere and there we come back to this topic of product identification.

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What does this Ecodesign Directive require with regard to this passport and, above all, what effect does it possibly have on medical device manufacturers?

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Yes, so

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Just like the M.D.R.

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an optical marking, an optically machine-readable marking is required.

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In the end, this is usually a QR code or data matrix code.

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QR and Datamatrix are barcode symbologies, Datamatrix with the L.

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QR code with the 3 pyramids and the QR code then typically leads to this information with a URL, but possibly also in other ways.

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And this information is then stored somewhere with the manufacturer or in the central database, in the central register.

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Yes, the Ecodesign Regulation has been adopted and the technical design is a standardisation mandate.

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I think it is a very excellent thing on the part of the Commission to say that we are the ones here

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the legal people and let the technicians do it to really solve the legal problems, to put it that way.

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No, that's why there was a standardization request and a joint committee was made between Sen and Senelec, i.e. the general standardizers and the electronics engineers, electricians, the G.T.C.

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24, also Joint Technical Committee 24,

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who have a year to shape it.

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And there is a group that does the marking and then there is a group security and a group database.

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So first of all, those who think about how this can work and from my point of view, interests or ideas from all kinds of corners come together.

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So that's natural, we have the retail trade with textiles, for example.

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With the Battery Ordinance, i.e. both the new Battery Ordinance and the upcoming Textile Ordinance, the Ecodesign Study, i.e. this product passport, will demand or already requires it.

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And there are a lot of people meeting there and that will be a standard that will probably have a lot of options.

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That means there will be a lot of opportunities to get rid of that.

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In the basic framework, the data comes from the manufacturer,

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where they are physically, whether the manufacturer manages it or some middleman or in the end as with Eudamed, the Commission is not yet completely out in my view.

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So at the moment it is very much in the direction of manufacturers, but we will discuss it for another nine months.

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By the end of the year, the die has been cast and then we'll see what happens.

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So we now have this part Register Database

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briefly discussed.

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In other words, you said that we don't know exactly how this will be technically implemented afterwards.

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Now you have just mentioned a second part, namely the part of the marking on the product, in our case on the medical device itself.

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What do manufacturers have to prepare for?

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So they need next to the, I'll call it M.

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D.

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R.

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I.

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V.

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T.

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R.

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U.

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D.

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I.

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another second barcode, for example.

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Yes, it is very often the case that

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regulations require a marking.

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We have tobacco, marine equipment, rail equipment, we already have a whole lot of regulations that require marking and, of course, the M.

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D.

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R.

00:09:12 Speaker 2

and the V.

00:09:13 Speaker 2

D.

00:09:13 Speaker 2

R.

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and of course it's always nice when we only ask for a marking, and I've been working on it with the Commission for a year and a half, and the Commission also has horizontal training courses, so they're really well organised.

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To drive it forward, to standardize it.

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So you can imagine Euler Med being expanded to include the D.P.P.

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or at least a URL where it is at the end or something, so that you can use the M.D.R.

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Code for this.

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This is currently very little on the radar of the joint committee, but there is currently an initiative that

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also there and I have also got backing from the Commission, so everyone is actually willing.

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What is mainly the topic is, as I said, there are an extremely large number of interests colliding there, so I don't know what will come out in the end, retail and industry and so and stupidly many are convinced that their solution is the only right one.

00:10:21 Speaker 2

Yes, that's what my father does, Heinrich Oehlmann, because he's simply, I'll say, a bit older and more sedate.

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As a technician, I'm quickly upset when some other abstruse ideas come up.

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And in the commission you also need people, for example the new man Mario.

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From Italy.

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You just need people who are a little flexible, a little big-hearted, and first allow 1 and 1 to be 20 and allow that to converge against 2 at some point.

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But it doesn't achieve anyway and you have to accept that in a European process.

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Yes, I often see the role of the German mentality very critically, because it is often very small-scale and very narrow-minded.

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The southerners are simply far ahead of us.

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Well, I studied in France, I have at least a little practice, but you can, you need a lot more to hold such a flea circus together.

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the new U.D.I.

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Man, he can do that too.

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So suddenly a completely different wind is blowing now.

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I will also show Eudamed in the hospital for the first time at Med Logistica and in 2019 all hospital representatives and so fled from the M.D.R.

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Committees and now we're slowly getting them back and bringing the focus back into the really technical and out of pure regulatory.

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So that's also a good development.

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For manufacturers, I understand you correctly, does that mean

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that they cannot prepare themselves concretely at the moment.

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For example, that they have to take a second label into account in production or product design, because we simply don't know at the moment whether a second, even optical feature is needed or whether the M.D.R.I.V.D.R.

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Coding U.D.I.

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is sufficient here.

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So this conclusion of mine is correct, that one should wait and see at the moment.

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Yes, definitely.

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So

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The Ecodesign Regulation is a meta-regulation.

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First of all, it shows, in principle, the principle and how it should work.

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Other regulations, such as the Battery Ordinance and the Textile Ordinance, then pick up on this and say: 'OK, according to the Ecodesign Regulation, it should be implemented.' The Battery Ordinance, for example, requires a minimum battery capacity of 2 kilowatt hours.

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That's a big e-bike battery.

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This means that it does not apply to medical technology at all.

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So, I can imagine that some defibrillator for a helicopter or something like that has a battery, but a normal one doesn't yet and of course no pacemaker or anything else.

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No, that is.

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there is currently no medical technology that is affected according to the ordinance.

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But we'll see how that develops.

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Textile Ordinance will come, there will be many ordinances that refer to this and where medical technology may then be affected.

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O.

00:13:20 Speaker 1

K., I tried, I don't think I quite understood it yet.

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So I just learned from you that it is a meta-regulation, so that it does not apply directly and then your statement that it does not usually affect medical devices,

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did this refer to the Ecodesign Regulation or to the Battery Regulation?

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Both.

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The Ecodesign Regulation can only be applied to products if they are prescribed by another regulation.

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Ah, OK, the battery regulation says here, you need a DPP according to the Ecodesign Regulation.

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Mhm, the Ecodesign Regulation itself does not affect any products or anything and there are regulations afterwards that just say, OK,

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Here is the principle, we prescribe D.

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P.

00:14:04 Speaker 2

P.

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in such and such conditions.

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Could it be that an M.

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D.

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R.

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in this direction, so that it also falls under this meta-regulation.

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I can imagine that.

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So medical technology was lobbied at the beginning to keep them out of all the stuff.

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This has been successful, for example, with medicines, but always with the argument that we have something of our own that is roughly equivalent.

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And one way to get medical technology out of there is to say, OK, we'll expand the M.D.R.

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around D.P.P.

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skills.

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So that's always the trade and at the moment I don't see that happening.

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Although medical devices are explicitly mentioned in the Ecodesign Regulation, right?

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Yes, yes, OK, but that means about M.D.R., that could come, doesn't have to come,

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However, they could also be affected by orthogonal prescriptions.

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You have just mentioned the Battery Ordinance as a concrete example.

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Yes, so we had a meeting at GS 1 the week before last and they are also very active in both regulations and they say we will look at medical devices from 2030.

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O.

00:15:15 Speaker 1

K., that's an all-clear.

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I think that's perhaps the most important statement for our listeners in this whole podcast episode.

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Yes, that's good news.

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If we're still in the world of the U.D.I.s right now, is there anything our listeners should know?

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Perhaps on the subject of Eudamed, do you have any information that should be considered?

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Yes, so Eudamed, so listeners are yes, are manufacturers.

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First of all, I would like to thank all the manufacturers for promoting Eudamed and so on, and that we have

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currently live more or less with the current Eudamed.

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I can imagine that many are in great pain with it, my sympathy.

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Nevertheless, it is actually the best thing that can happen to us.

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We have only one database in Europe, not by country or in Germany, perhaps by federal state, but it is only one and the Commission is making an effort

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really to do that well.

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You just have to understand the point of view.

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They are all regulators and with them, so I personally as a technician, I always try to see, yes, what works, what we can use in the end.

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I also do hospital logistics and such, what can I take at the hospital in the end.

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The regulators always ask what the requirements are and you have to teach them technique in small bites.

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that works out.

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I also invite the manufacturers and everyone, because

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To be active there and to influence, to report and so on.

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In my view, if I compare it with our German groups, the Commission is much better positioned, much more professional.

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Then, of course, I would like to say that the manufacturers must or should also put pressure on themselves as soon as, for example, the device module is probably activated next year.

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There are still 2 years left

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transitional period, but if you have an S.S.C.P.

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will have to do it obligatorily via Eudamed next year.

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So you have to have the Sprint Device Records in it.

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So the current plan is to tell everyone else: ‚Here guys, now only master data about Eudamed.

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No more special curls.‘ And you also have to tell the German implant register, for example: ‚Guys, you have the manufacturer and Rev number as keys, for example.

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That is not possible at all.

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We have UDI DI as a key.'

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there is also in the law, because the German legislator has tried to make it clear to them that as soon as there is something European, it has to be taken.

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And from my point of view, manufacturers must also put pressure on this to ensure that this happens and that not everyone drives their own special lock again in their state.

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And so we have to, Eudamed is a huge opportunity from my point of view and we just have to take it.

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I'm glad to hear that, as well as your optimism, which you have, because many manufacturers are a bit stunned.

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Besides all this procedure and ask yourself, how can it take so long to establish a database?

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And would a Commission and Notified Bodies have as much patience with the manufacturer as the manufacturer must have with the progress in the Commission?

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But they have just shown us what factors are involved, that regulation meets technology more and that it is sometimes difficult to find a way.

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But I have now heard a certain optimism from you,

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that you can make progress there.

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I hope I haven't overinterpreted them.

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No, no, so I'll say, look at the situation from a hospital, for example.

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No, the hospital has to be able to access master data somehow, there are more or less windy master data for that and now there is finally Europe-wide valid master data, where

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You can really say, as a hospital, I can now really know whether my medical device is approved or not and that is the valid master data.

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This is a monster step for the hospitals.

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So far, there has only been muddling around everywhere and each purchasing group and so does its own stuff.

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So, Mr. Jonah, I know if you remember, before we met, 10 years ago I sent you an e-mail where you criticized Eutemed and I wrote that I could cry.

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Yes, and we've always wanted to see each other.

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and we just have to let go of the German small-small.

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So always just complaining and have to think big and Eudamed is something big and will just help everyone and we have to take the chance.

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Yes, so that now again the federal government seems to be paralyzed again and and nothing is going on and so on and you in Germany

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If you are in the state, you are lucky and if you are there and in Saxony-Anhalt there is only a half-time office that takes care of it.

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So you have practically no support and stuff.

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So we have to get away with everything.

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But for me, Eudamed is clearly an opportunity.

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That's good news and I am.

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also a good final word on this whole topic.

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I'll summarize very briefly again, we have now actually highlighted 2 topic areas that even have something to do with each other, namely the topic area Ecodesign Regulation Slash Digital Product Passport.

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They gave us the good news that we can still relax as a manufacturer, because you simply don't know exactly what it means for the products.

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There is hope that you don't need a second label,

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We also don't yet know what exactly will happen technically on the other side, i.e. on the register database side.

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So there is no acute need for action yet and they have a passionate and very positive plea.

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Yes, ultimately also for the European idea, for standardization and thus also for the udders with us just given.

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Doctor Oehlmann, 1000 thanks for these insights that you have given us, which we would definitely never have been able to access without you.

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Thank you very much.

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A joy.

00:21:09 Speaker 2

Thank you, Mr. Jona.