Johner Institute

Amendment to the MDR Transitional Provisions

With Luca Salvatore, Prof. Dr. Christian Johner

Transcript

00:00:06 Speaker 1

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

00:00:14 Speaker 1

The pressure was probably too great.

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At least in mid-February, the EU Commission and then also the Parliament agreed that the transitional periods for the MDR would be extended.

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That's good news for now, but a lot of questions are now arising.

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So questions, who, who benefits from it at all?

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What has been extended here?

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What requirements do you have to meet?

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And to answer all these questions that have now popped up here, I invited our regulatory affairs specialist, Luca Salvatore, to get some clarity.

00:00:52 Speaker 1

And so I greet you, Luca, if you might say a few more sentences to yourself, then.

00:00:56 Speaker 1

we know you if we haven't known you yet and then we'll jump right in.

00:01:01 Speaker 2

Exactly, hello Christian.

00:01:02 Speaker 2

Exactly, I'm responsible for regulatory affairs at the June Institute and I take care of everything to do with M.

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D.

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R.

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and also F.

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D.

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A.

00:01:13 Speaker 1

Yes, you're exactly our man, because that's where we end up with these questions.

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Let's start with the basics.

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So I have already said in a way that there has now been a parliamentary decision.

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What is now

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the stand.

00:01:25 Speaker 1

So it's now active, live, pick up again very briefly.

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Exactly, so this draft of this amending ordinance, it has gone through parliament, so it has received approval, but now it has to go through the publication process.

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This means that only if this ordinance is amended in the E.

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U.

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Official Journal, it will enter into force.

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That could be the case in the next few days, we don't know, it may take a while.

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I guess at the latest

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Beginning of March.

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O.

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K., but it's a purely formal thing, nothing can happen now, exactly.

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K., that means that this will come into force in any case, that is then only certain, it is now only a matter of days.

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And yes, now the next question was, which products does this affect at all or who benefits from this new regulation, from this extension of the transitional periods?

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Yes, this is generally similar to the currently still existing transitional provisions,

00:02:21 Speaker 2

This means that these transitional provisions generally apply to medical devices under the M.D.R., which require a certificate from a notified body.

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These are precisely the products for which a notified body must be involved in the conformity assessment procedure, i.e. class 2 A.

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or higher and also those products that still fell into class 1 under the old guidelines, but were still classified under the M.D.R.

00:02:47 Speaker 2

classified higher, such as

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These include reusable surgical instruments, but also implantable custom-made class 3 devices.

00:02:56 Speaker 1

O.K., and what it often affects, the software manufacturers who fell into class 1 under MDD and are now catapulted to 2 A or higher by this fantastic rule 11.

00:03:08 Speaker 1

So that would also affect them, exactly.

00:03:10 Speaker 2

So also a lot of software manufacturers, that's true.

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O.K., so you can also say that there are manufacturers who have not yet

00:03:18 Speaker 1

certificate under the EU Directive.

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That's right, exactly.

00:03:21 Speaker 1

OK, now when you talk about these transitional periods, terms come up and maybe we really start with the definitions such as placing on the market, making available, selling and I think we have to have clarified them first, because our assumption is that many of the questions come from the fact that these concepts are not understood quite uniformly.

00:03:41 Speaker 1

Help us to get up to speed.

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So, what is a placing on the market?

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Yes, that's what you say

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Very important to really understand these terms.

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A look at the E.U. also helps.

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Blue Guide.

00:03:53 Speaker 2

Placing on the market is the first provision of a product on the E.U.

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market, the initial deployment.

00:04:01 Speaker 2

The provision is any supply of a product, whether for a fee or free of charge.

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Yes, that is, the placing on the market is therefore the first supply.

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Yes, this is typically the time when the product

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leaves the manufacturer's area of responsibility, for example by selling it to a dealer.

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This would then be the first provision and this point in time is relevant for the transition periods.

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Very important, this marketing always affects every single product.

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So this is not about the initial provision of a product type, but really the initial provision of a single product.

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So, it's called a term like first placing on the market

00:04:46 Speaker 1

does not exist at all or this concept is not used at all.

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Exactly, it doesn't exist, it used to exist in the MPG, but we're only talking about placing it on the market, making it available.

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OK, so there is an initial provision and there is a placing on the market.

00:04:59 Speaker 1

This is the first deployment and this does not affect product types, but the product instances.

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That's right, the instances.

00:05:06 Speaker 1

OK, what a deployment is now, you actually already said.

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You said that if it goes out of the manufacturer's area of responsibility, for example to the dealer,

00:05:14 Speaker 1

Now we have the concept of the sales rule.

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So now sales are the same as provision.

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Sell-off is then any further provision, so to speak, i.e. in English this sell-off regulation.

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This is now, for example, when a dealer still has many M.D.D.

00:05:31 Speaker 2

products in stock and then continue to provide them until they are commissioned by the end customer.

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O.K., so that means, have now clarified the concepts and now we can talk about what

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has now been extended at all.

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Yes, we have already clarified which products this affects.

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Now we still have to look, i.e. for the products that are affected, as you said, all products that require a notified body under the MDR.

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What are the new regulations here?

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So, what, what is the relief promised here?

00:06:00 Speaker 2

So, the new transitional periods now depend on the risk class.

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For Class 3 devices and Class 2 B implantable devices, it is now

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The new transitional period of the 31.

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December 2027.

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This means that legacy products, i.e. MDD-compliant products, may still be placed on the market until 31.12.2027.

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There is a small exception to the regulation, certain 2 B implantable products, these are the so-called with Well Established Technology, i.e. something like braces or sutures, they still have

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an extended transition period of an additional year, i.e. 31.12.2028.

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That is, also for other 2 B.

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non-implantable devices, class 2 A.

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Products, Class 1 devices with measuring function or sterile placed on the market, this additional year, i.e. 31.12.2028, applies.

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This date also applies to these former Class 1 products, which are classified higher under the MDR.

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In other words, reusable surgical instruments, a lot of software products.

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Now there is an additional transition period and that is the class 3 implantable custom-made devices.

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Here, the 26th

00:07:18 Speaker 2

May 2026.

00:07:21 Speaker 1

Oh dear, oh dear, but that means that what you said now always concerns the placing on the market.

00:07:26 Speaker 2

Exactly, it always concerns the placing on the market.

00:07:28 Speaker 2

It is perhaps important to add that there is no transitional period for the other Class 1 products, which continue to fall into Class 1 even under the MDR.

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These have therefore had to be used since 26.

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May 2021, i.e. with the start of validity of the MDR.

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O.K., maybe let's do it with an example.

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I am a manufacturer of software that was already Class 1 compliant.

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Then it means there is none for this software.

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But then there may be a transitional period if she were to fall into class 2 A now.

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Is that correct?

00:08:03 Speaker 2

That's correct.

00:08:04 Speaker 1

Yes, if she had stayed in class 1, there would be no transition period.

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Exactly, then it would have to be MDR-compliant by now.

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O.

00:08:11 Speaker 1

K., then we may look at another area, but now we don't get into the area of certificates.

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So there are actually several questions now, let's do the case first, a manufacturer still has a valid certificate,

00:08:23 Speaker 1

the one under this valid certificate, i.e. the old guideline certificate, is now important, would still be allowed to put a new product on the market.

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That is exactly what these transitional periods are all about.

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Now, of course, you can ask yourself, this M.D.D.

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Certificates, they were only allowed up to 26.

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May 2024.

00:08:41 Speaker 2

Yes, that's somehow the maximum validity date on these certificates.

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What happens to the certificates now, do they have to be reissued?

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No, this is not possible.

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the certificates remain as they are.

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But this new regulation says that even if the specified date has expired, these certificates will still be valid until the dates just mentioned.

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So it is said expired before this transition period or expired before 21: So all certificates are now renewed or does this end of the certificate have to have been in a certain time range?

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Exactly, so the rule is,

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the certificate is still valid until the entry into force of this amending regulation.

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00:09:28 Speaker 1

K., so it actually mainly affects the certificates, which now somehow, let's say, expire in March 2023.

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They are extended with this deadline quasi by Orde de *****, is that correct?

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That's correct.

00:09:40 Speaker 2

However, there is now another special feature for certificates that may have already expired, i.e. before they come into force.

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Yes,

00:09:47 Speaker 2

I can say something again in a moment.

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There are still general requirements at all as to when these transitional periods may be applied.

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Yes, O.

00:09:55 Speaker 1

K., so we have to go into it, let's do this bit by bit, before we dive into the details, another topic, that we can conclude this upper level.

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There has now been marketing, provision, sale, so that you may go into very briefly again about what exactly these transitional periods now concern.

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So that's it.

00:10:13 Speaker 1

maybe repeated it again and then closed it.

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So these transitional periods that I have just mentioned, 31.12.

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27 or 28, they really concern this placing on the market under the MDD or AIMDD, i.e. under the old guidelines, i.e. first provision.

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And then we have the issue of sales.

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Sale, you have the special feature, we currently still have in the MDR, that this sale

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i.e. any further provision only until 26.

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May 2025.

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That has now been resolved.

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This means that products legally placed on the market, i.e. a class 2 A until 31.12.2028, for example.

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product, may then be provided and put into operation beyond that and theoretically for an indefinite period of time, i.e. even after 2030.

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So, we don't have a sell-off policy.

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Now you have mentioned something else, namely commissioning.

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Do we still have restrictions for this?

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No, not that either.

00:11:13 Speaker 1

OK, so that means that in this, in this new ordinance or this amended one, we not only have an extension of the deadlines, but also an elimination of deadlines or concepts, as you just said, regarding sales and commissioning.

00:11:27 Speaker 2

Yes, exactly.

00:11:28 Speaker 1

OK, so with that we have already covered this upper level, so to speak.

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In our article, which we link, we also have a

00:11:35 Speaker 1

Including a graphic, such a decision graphic, you can understand again, depending on the product class, for example, at which deadline tremors land.

00:11:43 Speaker 1

But now you have already indicated that certain requirements must be met in order to be able to benefit at all and I think you would have to give us a little more details.

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Now it gets a bit more complex, exactly.

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So an important prerequisite, but one that is logical, the products must of course continue to comply with the guidelines, i.e.

00:12:04 Speaker 2

M.D.D.A.I.M.D.D.

00:12:05 Speaker 2

Remain compliant.

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Yes, this is an important prerequisite.

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Then, as we already know, no significant changes may be made to the interpretation or the intended purpose.

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For this purpose, a corresponding M.D.C.G.

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guidance, which describes exactly when a change is to be considered material or significant and when it is not.

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So, significant changes are not possible.

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Yes, neither of these is new at first.

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But now it goes even further, because now the amending regulation states that the products must not pose an unacceptable risk to the health and safety of patients, users, third parties or even to public health.

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So, now you ask yourself, yes, and who should test it, who should test it now, the manufacturers themselves, notified bodies or even the national authorities?

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A look at the MDCG guidance from December last year, i.e. 2022 deleted 4, may help here.

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Exactly,

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So, in general, the valid MDD certificate ensures that no unacceptable risk emanates from a product.

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In addition, manufacturers will continue to be monitored by the notified bodies during these transitional periods.

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00:13:17 Speaker 2

If serious deviations, major deviations, are now identified there, which could possibly lead to an unacceptable risk, then the notified body, and this is now in this M.D.C.G.

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inform the responsible state authority, for example a regional council?

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O.

00:13:37 Speaker 1

K., so only what you said must not be an unacceptable risk, which is actually not particularly surprising, because we have always had to check that in Post Market Surveillance.

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So, now I believe that what is new is the involvement of these national authorities.

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How about products that are not yet monitored by a notified body?

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So, how is it, a highly classified product, so to speak, do we have anything to consider again?

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We don't have a notified body, there are only the state authorities.

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Yes, of course they are allowed to stop by for an inspection, which has always been the case.

00:14:09 Speaker 2

Now.

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I wasn't quite through with the requirements yet, because there are others and that's interesting now.

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An important prerequisite for these transitional periods is that the manufacturers must be able to apply as early as 26.

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May 2024.

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We find this in Article 10 paragraph 9.

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This means that there is not much time left for that.

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Yes, another good year.

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So it is not enough just to maintain this postmarket vigilance and registration obligations of the M.D.R.

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which is already mandatory, but complete Q.M.

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system established until 26.

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May 2024.

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So this is an additional important prerequisite.

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So now complete means in the sense of Article 10, I suppose, and Annex 9.

00:14:58 Speaker 1

Exactly, and does this complete quality management system then have to be audited or certified by the notified body?

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So this is not yet about Annex 9, but really only this Article 10 paragraph 9.

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So it doesn't have to be certified by a notified body.

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Of course, we only did that with the M.D.R.

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Certification.

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That has to be established.

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Of course, there is also the question of who is checking this now, whether it is already compliant according to M.D.R.

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Yes, as I said, notified bodies continue to monitor manufacturers of legacy, i.e. directive products.

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now it goes even further and the manufacturers must also by this date, i.e. 26.

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May 2024, submitted a formal application for conformity assessment under the M.

00:15:41 Speaker 2

D.

00:15:41 Speaker 2

R.

00:15:42 Speaker 2

with a notified body.

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O.

00:15:45 Speaker 1

K., let me summarize you very briefly, because that was a lot of what you have there, so that we don't have anything falling down on the stack.

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So, we have said that we have extended transitional periods, but you can only benefit from them if conditions are met.

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These prerequisites include that the products do not represent a

00:16:00 Speaker 1

unacceptable risk.

00:16:02 Speaker 1

You have a complete Q.

00:16:03 Speaker 1

M.

00:16:03 Speaker 1

system within the meaning of Article 10 and they have submitted an application for conformity assessment.

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And I think we have to dive deeper into the last thing.

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So help us again very briefly, what is meant by it and there is also something like a written agreement.

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So it's the same if you could tell us more about it.

00:16:23 Speaker 2

Exactly, so that's where I'll start again.

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So this formal application must be made by 26.

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May

00:16:30 Speaker 2

24 and until 26.

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September 2024, a signed agreement with the notified body must then also be available, a contract for MDR certification, so to speak.

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What is that exactly?

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So with this application, this amending ordinance means this application for MDR certification.

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For this purpose, the notified bodies have their corresponding forms that must be filled in.

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But what is unclear now is

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by this date, only the application must have been submitted or it must also be correct, i.e. checked and accepted by a notified body.

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This will certainly lead to different interpretations again, perhaps also to disputes.

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Unfortunately, this amending regulation has not made that clear.

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We currently assume, if you take it literally, that only the application must have been submitted, but no validation must have taken place by 26.

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May 2024.

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Yes, that's extremely relevant.

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Well, we know from notified bodies that the correctness of the applications, so that it is 0% in the first run.

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This means that we often have relatively long processes until the applications have made it to a level of quality that is then accepted.

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So, we don't need to speculate about what this is due to now, because 0% is already relatively little.

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But that means that this is a very crucial question that you have raised.

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But you have already said that we assume that it is the motion and not the acceptance of the motion, because that is also at least how it is written in the amending ordinance.

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Perhaps another question in this context, does it have to be the same notified body under which one has already worked as under the guidelines, or is a change possible?

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A change is possible.

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Example, the current notified body is not yet under the M.

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D.

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R.

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designated.

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Yes, then of course you can't apply there at all.

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So in that case, a change would even be necessary, but even in general, a change is possible within these transitional periods.

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O.

00:18:32 Speaker 1

K., so now we have talked a lot about the interaction of the notified body, so to speak.

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Do we have anything else to consider with the state authorities?

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What else do they need to be involved?

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So according to this amending ordinance, this is not provided, unless, as I said, there are now major deviations during this monitoring period within the transitional periods.

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the notified body must inform the competent Land authority.

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Yes, but that's more something that the M.D.C.G.

00:19:01 Speaker 2

and not this amending regulation.

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I would say that then we have now made such a big, yes, breakthrough, and have now concentrated pri-

marily on the fact that at the time that this amending regulation comes into force, the certificate was still valid.

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Now let's take a look at a change of topic, what if that's not the case, what do the manufacturers have to do?

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Exactly, this is a special case.

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This means that if the certificate is a basic prerequisite for M.D.D.I.M.D.D.

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Certificate still had to be issued on 26.

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May 21, i.e. with the start of validity of the M.D.R.

00:19:38 Speaker 2

But it has now expired, i.e. before this new amending regulation comes into force.

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That is possible, then you can also benefit from these transitional periods.

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But there is now a prerequisite, either

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Here, too, there is a written agreement in accordance with Annex 7 of the MDR with a notified body, i.e. a contract for MDR certification.

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However, this must be done before the MDD certificate expires.

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Otherwise, it is no longer possible to do it afterwards.

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Otherwise, the only way to do this is to apply Article 59 of the MDR, which is the so-called special permit or special permit.

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or authorisation to place on the market with so-called non-conformities under Article 97 MDR.

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Yes, help us very briefly.

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So, are there any requirements that have to be met?

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How does that differ?

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So let's assume I'm such a manufacturer, what item do I see?

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Exactly, i.e. Article 59 Special Permits, which now grants the B for German manufacturers.

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Farm.

00:20:46 Speaker 2

We had seen that now in the Corona pandemic, there were for many products

00:20:52 Speaker 2

Special permits.

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But this is not a standard procedure if you now say, O.K., our M.D.D.

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Certificate has expired, we now need a special permit.

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So there must be good reasons for it.

00:21:04 Speaker 2

That's difficult.

00:21:05 Speaker 2

It is then more possible to apply these Articles 97 1.

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The point here is that placing on the market is still permitted, even if there are non-conformities.

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A non-conformity would be, for example, an expired certificate.

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Yes, there

00:21:21 Speaker 2

you then contact the respective competent state authority, which evaluates it, again no unacceptable risk must emanate from the product and then set a deadline by which this non-conformity must be remedied.

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So in this case then the M.D.R.

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certification.

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The

00:21:40 Speaker 2

What are these special requirements for manufacturers whose certificates have already expired?

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So, that means that some manufacturers almost get a second chance or a last chance to repair things again, but not all.

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So, as you said, if the certificate had expired, you didn't submit the application, then that was usually it.

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But I think then you really overslept a bit.

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Now we have talked a lot about placing on the market.

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There is still

00:22:06 Speaker 1

other areas, some of which you have already answered, have said, i.e. requirements for the balance sheet for post-market surveillance, which have already been directly valid or have to be fulfilled directly since 2021.

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Are there any other activities, so to speak, that are affected by the transition periods?

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I am now thinking of topics such as registration, i.e. U.D.I.

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OidaMed Stories.

00:22:26 Speaker 2

Topic U.D.I.

00:22:27 Speaker 2

OidaMed, there are also certain transitional periods, but they are not affected by this

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new amending regulation.

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That means they will remain.

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That is, in general, there is this U.D.I.

00:22:38 Speaker 2

Mandatory only for M.D.R.

00:22:39 Speaker 2

products.

00:22:41 Speaker 2

The registration obligation in OidaMed, on the one hand for economic operators, already applies.

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But there is also the obligation to register products, including legacy products, i.e. guideline products in OidaMed.

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But these transitional periods remain in place.

00:22:58 Speaker 2

In general, this period is

00:23:00 Speaker 2

as soon as it has been announced that Eudamed is fully functional, maybe next year plus 2 years you will still have time to register these products.

00:23:09 Speaker 1

Well, as you can see, the matter is relatively complex.

00:23:12 Speaker 1

There are various reasons, which we have now also highlighted.

00:23:15 Speaker 1

Well, one reason is, of course, that not everyone had exactly the same definitions in their heads.

00:23:19 Speaker 1

So placing on the market was a nice example of this.

00:23:22 Speaker 1

Then it was the dependencies on the class of the product, which was divided into class before M.

00:23:28 Speaker 1

D.

00:23:28 Speaker 1

R.

00:23:28 Speaker 1

and then with M.

00:23:29 Speaker 1

D.

00:23:29 Speaker 1

R.

00:23:30 Speaker 1

Then there were all the special cases, so to speak.

00:23:33 Speaker 1

Has the certificate expired?

00:23:34 Speaker 1

If so, when did it expire?

00:23:37 Speaker 1

Have I made an application?

00:23:38 Speaker 1

Has it been approved?

00:23:39 Speaker 1

In other words, a lot of case distinctions, so to speak, which make this construct relatively complex.

00:23:44 Speaker 1

Are there any other things that you think lead to confusion or make sure that there may even be different interpretations?

00:23:52 Speaker 2

Yes, the U.D.I.

00:23:55 Speaker 2

Duty, for example,

00:23:57 Speaker 2

Because, as I have said, a QM system must be established during this transitional period, according to Article 10 paragraph 9.

00:24:03 Speaker 2

And there it is mentioned, a procedure for the allocation of UDIs.

00:24:07 Speaker 2

This is now contradictory, because this UDI obligation actually only applies to MDR products.

00:24:11 Speaker 2

This will now lead to disputes again, in the hope that the MDCG will clarify this.

00:24:17 Speaker 2

But that can take months to years again.

00:24:20 Speaker 1

Well, that means a lot is regulated, but unfortunately we still have a few vagueness in it.

00:24:24 Speaker 1

So, you had at least 2 mentioned now in the conversation, now the U.D.I.

00:24:28 Speaker 1

topic and before that then the matter with the application, whether it is still being made now, must also be approved.

00:24:33 Speaker 1

So, there is still a lot of need for clarification.

00:24:36 Speaker 1

How can you now in this relatively complex situation, you and your team help manufacturers to be sure that they are on the

00:24:44 Speaker 1

compliant site and not somehow completely destroy yourself with all this regulatory madness.

00:24:51 Speaker 2

Yes, we are currently receiving a lot of questions about these transitional periods and we are of course always willing to support them as best we can.

00:25:00 Speaker 2

I can imagine that by far not all questions have now been answered by the podcast.

00:25:04 Speaker 2

Exactly, and as I said, it will take some time until probably new M.D.C.G.

00:25:08 Speaker 2

Guidance documents have been published.

00:25:11 Speaker 2

How we can support in general is, of course, now

00:25:14 Speaker 2

Yes, we have this hard deadline, now an M.D.R.

00:25:17 Speaker 2

compliant Q.M.

00:25:17 Speaker 2

system, by May next year.

00:25:21 Speaker 2

We can help, for example, to ensure that the Q.M.

00:25:24 Speaker 2

system and the technical documentation and also to check this M.D.R.

00:25:29 Speaker 2

Readiness, a kind of quick check, so that you are on the safe side that you can already use this

00:25:37 Speaker 2

in order to be allowed to use these transitional periods.

00:25:41 Speaker 1

You often help with applications, how necessary this is, I had reported earlier and what also achieves us a lot are questions or help on the subject of change.

00:25:50 Speaker 1

Am I still allowed to do that now?

00:25:51 Speaker 1

Is it already significant?

00:25:53 Speaker 1

Isn't it significant?

00:25:54 Speaker 1

If it would be significant, what do I have to do, so to speak, to get exactly this M.D.R.

00:25:59 Speaker 1

Readiness?

00:26:00 Speaker 1

Yes, those are the questions, as I said, that's what we're here for.

00:26:03 Speaker 1

We like to do that from the bottom of our hearts, that's why we exist.

00:26:06 Speaker 1

Mr. Luca, I can only say thank you very much for giving us an insight into what I think is still a relatively complex topic with the transition periods.

00:26:14 Speaker 1

So maybe take a look at the website, we have updated it accordingly and just get in touch, so far we have solved every problem.

00:26:22 Speaker 1

Luca, thank you very much again.

00:26:24 Speaker 2

Thank you, Christian.