Annex XVI Products

With Luca Salvatore, 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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The MDR and the IVDR have introduced a concept in the Common Specifications, the common specifications, that the EU directives did not yet know.

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There aren't very many Common Specifications, but now for the 1.

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December 2022, one has now been published, one on medical devices or, more precisely, on products without a medical purpose.

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So, these are the products that are also regulated in this Annex 16 and that is exactly what we want to take as an opportunity to take a look at them today.

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Which products does it affect at all?

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How do the regulations of these products differ from the other medical devices?

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What should a manufacturer pay attention to in this product class in general?

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And for this purpose, I have invited Luca Salvatore again, our expert on regulatory strategies.

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Many already know him, but because maybe all of you know him, I would say, Luca, give me a very brief overview of yourself and what you do here at the Jona Institute.

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Hello Christian, hello dear listeners, I am responsible for the following areas at the Jona Institute:

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Regulatory Affairs for medical devices, now new, but also for products without a medical purpose.

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This means that we take care of all regulatory issues, be it on specific approval procedures, other regulatory requirements, basic requirements, i.e. the overall package from both the E.

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U., but also internationally.

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Yes, so of course you are exactly the man we need here now to understand regulatory requirements, now just to these

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special product class.

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So maybe let's get started in a very relaxed way, what kind of products are we talking about anyway?

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So, what are products anyway that fall under the M.

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, i.e. under the Medical Devices Regulation, but which have no medical purpose?

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Can you give us a few examples?

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Exactly, so these products are listed in Appendix 16.

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Currently we find 5 product groups there.

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You can

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roughly speaking, these are products with more cosmetic or aesthetic purposes or other non-medical purposes.

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These include, for example, colored contact lenses or subdermal implants, i.e. something like horn implants, but also breast implants.

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Dermal fillers, i.e. something like hyaluronic acid injections, bodyforming devices for liposuction, devices for hair removal or skin rejuvenation or non-invasive devices for magnetic or electrical stimulation of the brain.

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They are now obviously regulated.

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So before we dive into these regulations, what do you think was the reason for the legislator to take care of this product class now?

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Yes, so definitely the risk profile, which is quite similar to that of medical devices, or the features or functionality.

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For example, aesthetic contact lenses have similar features and probably a very similar risk profile as medical contact lenses.

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that is the reason.

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And perhaps an important note, this Annex 16 list may be expanded in the future.

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So, other product groups may be added, again on the condition that they then have a similar risk profile or similar characteristics as corresponding medical devices.

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In the end, you can just say,

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the same reason why the person who wrote it in the first place, namely to ensure the safety of the patients.

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So that's a big driver that led to this.

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But of course there are differences now, so possibly in terms of this effectiveness.

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But before we go there, maybe a step back.

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So what are these regulatory requirements that this particular class of products must meet?

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Maybe we divide this by first looking at what is the same and then perhaps in the second step, where does it differ from the other medical devices?

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With pleasure, in principle

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manufacturers of Annex 16 products must meet the same requirements as medical device manufacturers.

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Because the MDR talks in general or talks about products in general.

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By this she means medical devices, accessories for medical devices and these Annex 16 products without a medical purpose.

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This means that manufacturers must comply with the same obligations that we find in Article 10 of the MDR.

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So, for example, you have to set up and implement a QM system, including risk management.

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You will need to conduct a clinical evaluation.

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You must prepare technical documentation in accordance with Appendix 2 and 3.

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In the same way, you will have to go through a conformity assessment process, with or without a notified body, depending on the risk class.

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You have to meet UDI requirements, post-market surveillance requirements, reporting obligations, so a whole lot and of course the corresponding ones

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applicable essential safety and performance requirements set out in Annex 1.

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For God's sake, that's probably the fun of putting your products on the market.

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You said, so essentially exactly the same thing.

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I imagine it is a bit difficult now, especially with such a risk-benefit.

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Are there now areas where there are exceptions or where you do not now have exactly the same obligations as the manufacturers of medical devices with a medical purpose?

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Yes, the

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Have you already mentioned the corresponding topic?

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So, how can you prove a clinical benefit for a product without a medical purpose?

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That is unlikely to be possible.

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This means that a clinical evaluation is required, but here the focus is on proving safety and performance and not on clinical benefit, which does not exist.

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Yes, but here, beware, there may be products

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which are considered both medical devices and Annex 16 products, such as breast implants for medical and aesthetic purposes.

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Yes, in this case the clinical benefit must certainly be proven accordingly.

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K., what you say is very important.

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It's not either you have an Appendix 16 product or a non-Appendix 16 product, but it can be a product that can fall into both classes.

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Exactly, yes, that can be possible.

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Wow, that's of course particularly challenging, although probably if you

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The requirements for normal medical devices are met, implicitly those for non-medical devices should also be met, I guess.

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You just mentioned that we cannot now focus on the proof of benefit in the clinical evaluation for these particular products.

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How do you deal with risk management now, where we also have this risk-benefit discussion, where we have to define acceptance criteria?

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What would be your tip?

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How do you argue there?

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In general, Appendix 1, i.e. the essential safety and performance requirements, require a positive benefit-risk ratio.

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But we have no medical benefit here now.

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Thus, the manufacturers have to determine the risk policy and acceptance on a different basis.

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And here it helps to take a look at the joint specifications that have just been adopted.

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It then states, for example, that manufacturers only consider the residual risks to be justifiable.

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If, for example, undesirable side effects are only temporary in nature and no surgical interventions are required now, for example, to prevent a life-threatening condition or illness now.

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Otherwise, the corresponding risks would not be justifiable.

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Of course, this will be difficult for the manufacturers, because in the very, very, very worst case, something difficult can always happen and that you can then have such a discussion.

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In the end, we are probably in a similar topic again, as we already had with the software.

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We always talk about risks, but these guidelines talk more about severity levels and less about probabilities.

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And we only have to consider the probability.

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small enough and then we end up with a sufficiently high damage again.

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Or how do you see it?

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Or are there any hints in this new Common Specification on the subject of probabilities?

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Unfortunately, there is no such thing and it will be exciting to see how this will be interpreted accordingly by the notified bodies and authorities involved.

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But I think we can provide good support there.

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Also.

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If I may now address another difficult topic, namely classification.

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We find them in this appendix eight.

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The MDR now in this case.

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How would one proceed with the classification?

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Because it's often about things, like: Yes, is this something diagnostic or is it something therapeutic?

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Yes, with these case distinctions.

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but if you don't have one or the other, how do you come up with a rule that is not entirely unimportant, for example to be able to determine the requirements for the Wellens stamp?

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The classification rules according to Annex 8 of the MDR also apply to Annex 16 products.

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But now there is a problem, especially rules 9 and 10 for active therapeutic and diagnostic products.

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They assume a medical purpose, which we don't have here.

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For this reason, as of 1.12.

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at the same time as the common specifications, another implementing act was adopted, precisely on the reclassification of the corresponding products.

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For example, the so-called bodyforming devices are now addressed, which are or therefore fall under class 2 B.

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Skin rejuvenation products fall under class 2 B if they are only for hair removal, 2 A.

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And then we have these products for transcranial stimulation of the brain, which are assigned to class 3.

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Maybe now for me as a layman, what is bodyforming, example of a bodyforming device?

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So it's about cosmetic products, in this case liposuction.

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There I am now, I'm supposed to be a security guard in there, hopefully it doesn't have to be.

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Now you just reported, on 1.12.

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it has now been published.

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Are there any transition periods?

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Well, the question is almost to be understood in two senses.

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Well, we have once moved from guideline times to M.D.R.

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times and now then before and after this 1.12.

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So, in summary, what transitional provisions should the manufacturers of these products observe and what transitional periods do they have to observe?

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So, there are special transitional provisions, depending on different constellations.

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In general, the common specifications were published on 1.12.

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published in E.U.

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Official Gazette 20 days later, i.e. on 21.12.

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they shall apply.

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So they are not valid until half a year later, i.e. on 22.6.

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23 So, now there are further transitional provisions and that depends, for example, on whether the manufacturer has a clinical

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Testing planned on humans or perhaps already carried out and a notified body must be involved in the conformity assessment.

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This means that there is a product higher than class 1.

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Then there is a five-year transition period, i.e. until 22.

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June 2028.

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However, the whole thing is linked to certain conditions.

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This means that the product must be purchased within the next six months, i.e. by 22.

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June 23 for the first time.

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have been lawfully marketed and comply with the relevant applicable legislation, such as M.D.D.

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No significant changes may be made to the interpretation or intended purpose and by 22 September 2019 at the latest.

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June 2024, a complete application for clinical evaluation must be submitted to the authority and this must also have been confirmed.

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And this clinical evaluation must be carried out at the latest

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on 23.

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December 2024.

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That's not all, because a contract must also be signed with the future notified body for conformity assessment, by 23.

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June 2026.

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That is a possible constellation.

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For God's sake, that's

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complex.

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So that's why we'll write it down in an article later.

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But let's stay with these challenges that they have now.

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Well, I would guess that they will have a hard time finding the right transition period for the various activities for themselves.

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What other problems do you suspect the manufacturers will have to deal with or which of these problems do they have a particularly hard time with?

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So, I generally suspect that many manufacturers don't want anything from the M.D.R.

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knowledge and also

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certainly not yet aware of the adopted Common Specifications, i.e. the regulations.

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Some may already know each other, but not in detail.

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So maybe they don't have the expertise, yes, to create technical documentation or a Q.

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system, as well as perhaps complying with relevant standards, such as ISO 14971 for risk management or ISO 10993 for biocompatibility.

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K., so what you're saying is

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Ultimately, they are at the beginning, actually like a new manufacturer of medical devices, and immerse themselves in a world they have never heard of.

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And we see every day how complex that is.

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We have been doing nothing different for 20 years and are always finding new corners where there are new challenges to solve.

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Of course, that's really a lot that they have to pay attention to, what they need to know.

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Well, you just said that the amount of regulations alone is overwhelming.

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An M.D.R., I think that was 175 pages, does a 60 also apply?

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601 Certainly for the active products without medical purpose.

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K., another plus 400 times.

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So that means that this is simply the amount that really has to be managed.

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I guess it's a hurdle that very, very many of these manufacturers can't overcome.

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Maybe that's also the goal of the authors of the M.

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to ensure a market shakeout.

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For those who now want to go the way anyway, i.e. despite the obvious

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high hurdles.

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What would you recommend to them?

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What should they do now?

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Maybe also, how can you help concretely with your topics?

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Just as generally, I would say familiarize yourself with the regulations as quickly as possible, build up expertise, research relevant standards of equivalent medical devices.

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Ideally, there is already some kind of technical documentation or a Q.

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system, then perform a gap analysis here, identify the gaps, define tasks and thus create a project plan for

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the M.D.R.

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Certification and very importantly, get in touch with the notified body in good time due to the long waiting times.

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Wow, do you know if the notified bodies are already prepared for these product classes?

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Yes, this can also be found on the websites of the notified bodies.

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There are already certain sections for these Annex 16 manufacturers and a corresponding contact form, where you can get in touch with the notified body.

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Good keyword on our website or in the show notes you will also find the contact details of us from Lucas Salvatore and his team.

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Get in touch if you have such a product and know if you are at the very beginning and don't know what to do.

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Or maybe you are already, and we hope that is a lot further along and have very specific questions, such as clinical evaluations, how to deal with them, classification, transitional periods or everything that we have just discussed.

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So there we are

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willingly.

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Yes, Luca, it remains for me to thank you again very much for being there.

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Many, many thanks and dear listeners, more information on our website in the technical article, which we have also linked to you in the show notes.

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And if you have any questions, please contact us.

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Bye and thank you very much.