

Last resort: special permits

With Luca Salvatore, Prof. Dr. Christian Johner

Transcript

00:00:05 Speaker 1

Medical Device Insights.

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A podcast by the Jona Institute for medical device manufacturers, authorities and notified bodies.

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I'm sure you've all noticed how the EU is trying to counteract.

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Unfortunately, the fact that more and more products do not disappear from the market and manufacturers give up trying to get through all these conformity assessment procedures and the extension of the transitional periods have not yet solved all the problems.

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And now there are other approaches that the EU at least allows or sometimes perhaps even advertises a little.

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And it's about this topic, kind of like special approvals.

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And in this podcast we clarify what it is now and.

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from special approvals and special releases and Article 97 have everything to do with it.

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So let's solve that and I had invited Luca Salvatore again.

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Luca, you are already in this area, maybe a very short ramp-up for those who don't know you yet.

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Exactly, hello Christian, so I am responsible for Regulatory Affairs and currently we are increasingly dealing with the issue of transitional periods and in this context also the

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Special approvals.

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Yes, so let's take a look at what it's all about.

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Well, there is always this concept of special approval and there is a concept of special approval.

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Help us to unravel this so that we don't confuse anything.

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Exactly, so that you don't mess anything up, I'll first explain what a special release is.

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Special release is a term from ISO 13485, i.e. from the QM standard.

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This is about how manufacturers deal with non-compliant products, especially before delivery.

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That is, we are talking about products that now do not meet their specification or requirements.

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This can be something harmless, such as a blemish in the paintwork of a device or something that can now have an impact on safety or effectiveness.

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So in the worst case something like a faulty sterilization before delivery.

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So, now ISO 1385 says that manufacturers are allowed to accept products with non-conformities via special approval and place them on the market in justified cases.

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This is what the special release is all about.

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However, this is not welcome.

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So, it should not become the standard to bring non-compliant products to the market.

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Otherwise, something is probably going on with the Q.

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M.

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system is fundamentally skewed.

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This is the special release.

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But now we want to talk about the special admission.

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This is a term from the M.

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R., specifically Article 59.

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It correctly reads: Exemption from the conformity assessment procedures.

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This Article establishes the competent authority or the competent authority of the Member States

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authorised to authorise the placing on the market of medical devices without having undergone a regular conformity assessment procedure.

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This means, so to speak, a placing on the market without C.

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E.

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Marking.

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So normally you will say, that's exactly what the legislator doesn't want.

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But now he explicitly writes it into the law, what is the background or what does he want to achieve with it?

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In this way, the legislator wants to create a possibility, especially in emergency situations, for example if there is an urgent medical need and this is not

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can be covered in the short term to ensure the availability of necessary medical devices.

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A good example was the corona tests during the pandemic.

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There are similar procedures in other countries as well.

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For example, the F.D.A.

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has its Emergency Use Authorization, which is equivalent to such a special authorization.

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The aim is to counteract supply bottlenecks for urgently needed medical devices.

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K., makes sense, the legislator opens the door a bit like that and that's what you can now do with the supply bottlenecks caused by the M.

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R.

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to threaten themselves, perhaps to take a little counteraction.

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So, what have they regulated now?

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So, I think you probably have to meet some basic requirements, or what is in this article?

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So it is precisely regulated in Article 59 MDR and then again nationally.

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In Germany, this is in the M.

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in paragraph 7.

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The basic prerequisite is that there is a need situation.

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This means that manufacturers must submit an application for special approval, which must certainly be sufficiently justified.

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The authority then checks whether there is a corresponding supply bottleneck, whether the product is really urgently needed for health care.

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It will also check whether there are alternative products on the market that could be used.

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Then you certainly won't get away with it.

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It is also checked whether the product or similar products pose serious health risks, for example

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By analysing and evaluating information from market surveillance.

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In the positive case, a special approval will then be granted.

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Perhaps also important: As a rule, it is then temporary.

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for a limited period of time.

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So in the end, it is again a risk-benefit assessment that you make, to assess the risks, also in comparison of course to the possible alternatives or even the benefits.

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Yes, what if we don't put the product on the market, we have alternatives.

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That makes sense to me.

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What should manufacturers do now or which manufacturers are affected by it now, when does it make sense?

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In general, it makes sense to use manufacturers who may have niche products, but who are urgently needed and perhaps the

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just not the M.

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certification.

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I'll say something about that in a moment, because there is an alternative option to this special approval.

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K., what would you have to do now?

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So, if you assume now, yes, I have a product to which there are no alternatives, the supply of a certain indication is not given.

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What would be their next steps?

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So apply in general, it is informal, at least in Germany.

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This is the case in Germany with the BfArM, with certain I.

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V.

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D.

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Products

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the Paul-Ehrlich-Institut is responsible for this.

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The application must contain information about the product, the manufacturer.

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Very important, of course, is the justification of the necessity for the marketing of the product and certainly the authority will also demand evidence, namely on the safety and efficacy of the product.

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So we might even look at technical documentation and thus perhaps take over a bit of the task that would otherwise be a notified body.

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It will not be possible to submit documents exactly, i.e. something like a risk analysis, certain test certificates, they will be required and that is indeed the case, a kind of assessment of the technical documentation, even if it may not be fully M.

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compliant.

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Yes, because otherwise we might have been able to go the way completely at some point.

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What else should manufacturers consider, what pitfalls should they avoid at all costs so that they can actually benefit from this article?

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Yes, it is very important that this special authorisation is only valid nationally, i.e. in the Member State in which it was applied for.

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This means that a marketing in other E.U.

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Member States is therefore not so easily possible.

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Yes, the product does not have a C.E.

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Labelling, that's important.

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As a rule, therefore, no free sales certificates can be issued to third countries.

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So, that can then make it more difficult to get approval in other countries.

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There is a possibility, because the

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The authority must inform the other member states and the EU Commission of its decision, and the EU Commission can then extend this special authorisation to the entire EU internal market by means of delegated acts.

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That would be another possibility.

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But it doesn't sound like such a very quick variant to cover it in moderation, at least not at the EU-wide level.

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Now you had just hinted at an alternative, yes, to the special approvals, and you talked about this Article 97.

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Help us very briefly what this is about, what the difference may be and when your action under this Article 97 would occur.

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Article 97, which confers certain powers on the competent national authorities in the context of their market surveillance activities.

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So now an authority determines that a product is not compliant with NDR, then it can demand that this non-conformity be remedied.

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To do this, the authority must carry out an assessment in accordance with Article 94.

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This means that it must assess whether the products pose an unacceptable health risk.

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If this is not the case, but the MDR is not fully met, then it may set a deadline under Article 97 to remedy this non-conformity.

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The procedure is now currently under discussion with the transition periods from MDD to MDR, because the MDCG had proposed to use this Article 97 if an old MDD certificate was now used.

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before obtaining an MDR certificate and thus there is a non-conformity.

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This is also contained in these new transitional provisions that we reported on last week.

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This means that this would be a possibility of applying Article 97, if an MDD certificate now expires before the new transitional provisions come into force, then Article 97 would be applicable.

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perhaps briefly the advantage in contrast to the special approval that the chances of success are probably higher.

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In Germany, the state authorities, i.e. the regional council, are responsible for this, and they will probably be burdened more heavily, then by this decision under Article 97.

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The advantage, however, is that only one authority decides for the entire E.

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Single Market.

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Yes, that means you can continue to use the product with C.

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E.

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License plates

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E.U.

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widely marketed and free sale certificates can also be issued.

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So I hear it like this, if you actually want to bring a new product onto the market for which there is somehow still a need, i.e. a need that is not met, then it sounds a bit more like a special approval and if you have already got a product on the market in compliance with the guidelines and now you are making difficulties with the certificate, so to speak, because it happens too early, so to speak,

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Then Article 97 is more likely to be the way to go.

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Did I understand that correctly?

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Exactly, you have, you have summarized well.

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Yes, because the chances will be higher just like that.

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You have already mentioned a few points that you have to pay attention to.

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So in both ways, yes, both in the case of special authorisations and in these Article 97 applications.

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Ultimately, how can you and your team help with this?

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So, first maybe choose the right path and then get it to the end successfully.

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How can you support this?

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Exactly, so we can support by first looking at what is available now, what is the status of the certification and what kind of product it is, so that we can already make an assessment, which way is sensible and possible, yes, special approval, setting a deadline according to Article 97 or, in the best case, we don't need either, because the manufacturer benefits from the new transitional provisions that will soon come into force.

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K., i.e. ultimately in the decision-making process and, depending on which path one takes, in the provision of the corresponding evidence, be it proof of need or proof of conformity according to M.

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R.

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or I.

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V.

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D.

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R.

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Yes, wonderful.

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So, anyone who is in this note, so to speak, we hope that there are very few, but everyone who is in this situation, having to make such a decision, at the moment is ultimately stuck with the legally compliant marketing of their products, can simply contact Lukas Salvatore, we have

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our contact details or his contact details are attached at the bottom of the show notes as always and let us know if we can solve any problem.

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Luca, thank you very much for this podcast.

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You too.

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Thank you very much, Christian.

