MDR Certifications at BSI

With Dr. Axinja Wolf, Prof. Dr. Christian Johner

Audio File: BS-BSI-V2.MP3

Transcript

00:00:00 Speaker 1

And we have been accredited since December 24 and can carry out ISO 42001 certification.

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

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78 years after MDR and IVDR are now in operation, many things are returning to normal and

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I hope that many notified bodies have slowly cleared the biggest mountain.

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But whether that is really already the case, I would like to clarify today.

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And for this I have been informed by B.S.I.

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invited Doctor Wolf, who was a member of the B.S.I.

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and also makes sure that there are new projects, new approval projects at B.S.I.

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And we just noticed that we even

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both have a Konstanz past.

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So for me it's not even the past anymore, even the present.

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Ms. Wolf, how did you actually feel about B.

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S.

00:01:02 Speaker 3

I.

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So, you have studied non-notified body, so to speak.

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How do you get to the notified body and what are you doing there at B.

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S.

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I.?

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Yes, so thank you very much in advance for the invitation to the podcast here.

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Yes, how do I get to B.

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S.

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I.

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It's a long story.

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I'll make it short, I've worked in the medical technology industry for over 15 years, mainly in dental companies, including Dentsply Detré in Constance.

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So, I'm referring to our shared history with Constance, where I've always liked to be and am and then I'm really interested in the dental industry, medical technology industry

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to the B.S.I.

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and am now working in sales.

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In the DACH region, this means that if a company applies for product certification in accordance with the C.M.D.A.

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or U.K.C.A.

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or for a Q.M.S.

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Certification according to ISO 13485 or M.D.SAP, then I am the first point of contact for customers or medical technology companies, so to speak.

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Yes, you will probably always hear the same question: Do you still have capacity at all?

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If so, how long do we have to wait?

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How long will this whole procedure take?

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What would you say now, not only from a sales point of view, but also when you observe how such projects then start and run, what would you answer to these two core questions?

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In other words, according to capacities and throughput times.

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Mhm,

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For more than a year and a half, we have had free capacities in the area of product certification, i.e. in accordance with the C.E.M.D.A.

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For the Q.M.S.

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Certification we have never had bottlenecks, so we always had free capacities, by the way.

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And as a Full Scope Notified Buddy that operates worldwide, we cover all product classifications and all product categories of medical devices, but also in vitro diagnostic devices.

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And I'll say, typically a C.E.M.D.A.

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Based on our experience, the certification process takes about 12 months, 12 to 3 months on average.

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Start-ups need a little more, I admit.

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They often need 13 to 14 months, because they often go through it for the first time.

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And it is our C.E.

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The certification process is structured in such a way that:

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that we first do the reviewer, then a first completeness check and then chronologically follow 3 rounds of questions.

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The reviewer then usually recommends the C.

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E.

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certificate and then there is another internal review with us, so that after about 6 weeks after this so-called panel review is completed,

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the customer then has his C.

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E.

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certificate for his product in his hands.

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That's good news, I'd say for now.

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So I even have 2, there are capacities, the second, it doesn't go indefinitely.

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Now you have already hinted at it, you can't give a fixed period of time, i.e. somehow exact to the day, because there are different parameters.

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For example, you just said that startups sometimes take a little longer.

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What can manufacturers do,

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so that they can get through it as quickly as possible.

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One could perhaps also ask the question differently, what are those doing right and well who get through faster and what are the things where the start-ups might still make a bit of unnecessary difficulties for themselves.

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So those would be the tips to get through it quickly.

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So, one of the main tips is actually to contact a consultant medical device company like you at an early stage, that you turn to a renowned consulting company like the Johner Institute in order to get your project, i.e. the new product development with product launch, off the ground at an early stage, so that you feel well advised in various aspects at an early stage.

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in order to then practically place the medical device in the E.

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U.

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market, what regulations are necessary and also to consider which documents must be included in the technical documentation.

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That is, and which examinations, especially clinical evaluation, is such an aspect, it is very helpful to have a consultant at your side.

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I really have to be honest about that, it contributes a lot to the success

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to general success, but also the aspect of getting market access effectively and quickly.

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Yes, what we observe or why we believe that we can always help, these are often very fundamental questions where you have to have clarity.

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So that often starts, it is often repeated, but unfortunately it is also the case, the clarity, what should this product really be able to do, what should it do, which patients should it help, what are these medical claims, these are often

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Or ideally even things that are expressed quantitatively.

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Yes, for example, we manage to reduce bleeding by 72 percent, the duration, for example.

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In other words, that we have absolute clarity about it, because otherwise the foundation will not be created.

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And once you have that, then you can go into the regulatory strategy and the clinical strategy with yourself.

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And often, as we have observed, if it does not flow smoothly, then these mistakes have been made very early on.

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So this clarity was not there.

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Sometimes, of course, it is simply experience and competence topics.

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Suppose we have already prepared a customer quite well.

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Are there a few best practices on your side that would help to go through the process as quickly as possible if it is already in your case?

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Or what hurdles can manufacturers remove at this stage of the process?

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So, we have 2 ways to do the certification, so to speak.

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So, that's the standard way, I said, it takes about 1213 months and then we have a so-called Interactive Dedicated way.

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It's also a bit more expensive, I have to admit, but it helps that we have the process

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more predictable.

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Of course, the other side always has to play along, we can then be faster, we spare slots, special slots for the customer, are more accessible and what does the interactive mean, that's brand new now, we've only been offering it for a few weeks, to the dedicated, so to speak, we build together with the

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customers in MS Teams, so that they can write in questions at any time, regardless of whether it's an official Q&A session or not, that they can ask questions, for example.

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I'm not sure if I can get the TechDoc now in the point where a point is after A.

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or B.

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What would B.S.I.

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Accept?

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Rather A., version A.

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or B.?

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And then someone can immediately respond to the channel, the responsible project manager, whom we call Scheme Manager, because everyone gets him, every company gets a Scheme Manager.

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who leads through the product certification, as the main contact person, so to speak, and who then answers the question immediately, so that you don't have to stop in your work as a customer, but can continue working right away.

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And that makes the whole process faster and in the end, as I said, more plannable.

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We can't say now how many weeks or months faster, that would be spoken out of the crystal ball.

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but it is more predictable, more effective and faster in the end to the end.

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So, what you just said, to select a variant by the right model for you, if it has to be done very quickly, then you take a little more money in your hand and then you reported, then you have faster response times, your own slots, your own channel.

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So by open you probably meant, i.e. open between the manufacturer and you, not open to the outside.

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Exactly, yes, between the manufacturer and B.S.I., an open M.S.

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Teams Channel,

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so not in public, in public exactly, so.

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Of course, it makes reaction speed.

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So they probably won't want to and can't give any figures, you can say by what percentage the prices for this accelerated service are higher, such a range.

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Or 2 to two and a half times more expensive than the standard price, you can say that.

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Our prices can also be found on our website

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So we are very transparent, you can find our prices and also the lead times.

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That is, we call it lead times, the waiting times, how long it takes until we then receive the first review or the Q.

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M.

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S.

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Start an audit.

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We are very transparent about that.

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You can find all the information on the website.

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Exactly, and an addendum, sorry, another addendum.

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this dedicated process, you can also start with Standard, with the Standard way and at a later point in time you can switch to Dedicated, Interactive Dedicated, if you can foresee better, oh, at a certain point in the project I want to be faster.

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So, you can still decide to switch to Dedicated later.

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Exactly, what other tips would you have for start-ups, because

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we all want to promote them in particular, because there is an incredible amount of innovation and enthusiasm in it, which should also come to the market afterwards or the products that result from it.

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Do you still have any thoughts, recommendations for these young, innovative companies?

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Yes, as I said, to actually turn to Consultant, to you, to the Johner Institute, in good time.

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Startup area can be, what I also experience, software, medical devices with and without artificial intelligence, also to contact us as a notified body at an early stage, let's say.

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I always say, preferably 15 months before the market launch.

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That would be my tip, because we need these 1213 months at least.

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I would give that and what is also important for us is the prerequisite that the TechDoc must be written in English, that it must be available digitally.

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We don't specify formats, we're not allowed to do that at all, because of the conflict of interests, but it has to be submitted digitally and in English.

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That would be important and, above all, complete.

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I have also been asked several times, can't we submit module-like when we have finished a part, module-like,

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Unfortunately, that is not possible.

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So, we only accept them in advance, in full at a certain time and then please submit them completely.

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Exactly, but these are important tips.

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Yes, so come in time and then please submit everything and please do so in English.

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Of course, this is important for startups to know.

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Perhaps from our experience, startups are almost by definition often relatively young and small companies,

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But even as a young and small company, you need certain basic resources, otherwise it won't be successful, because certain roles have to be filled.

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Yes, so we need people who are familiar with risk management.

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We need people who are fit in regulatory affairs.

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We need people who can take on the role of P.R.C.

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for example, the quality management officer.

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And the hope that you can now burden everything with one person,

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this plan does not always work out optimally.

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So another tip, perhaps especially for startups, is that you need a certain amount of basic funding, basic momentum, to be able to get through this process.

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Yes, they had just talked about it, yes about different product classes, that they all support them, what is there

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for you, while we're talking about start-ups and new things, what else is new on your site that might be interesting for listeners?

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Yes, thanks for the question, that's very important, maybe especially for start-ups in the field of software, medical devices with A.I.

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and we are also in the process of digital transformation and the E.U.A.I.

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Act came into force last year and

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And we, the B.S.I., have been building a, a so-called third pillar, I would call it in our country, a Notified Butty Artificial Intelligence since 2023.

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And we have been accredited since December 24 and can carry out ISO 42001 certification.

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This is the standard, the world's first international standard.

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I've always said Standard, in German they say Norm for A.I.

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Systems for the establishment and improvement of an A.I.

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Management Systems in an organization.

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This deals with the requirements and guidelines, so to speak, in order to manage A.I. responsibly, ethically and effectively.

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in the different contexts and applications.

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and we are already accredited and the B.S.I.

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has been able to carry out certifications since last December and we are already doing that.

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And this means that you are not only interested in medical devices or I.V.D.

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manufacturers of interest and relevance, but for all those who have an A.I.

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management system, if I may call it that.

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Yes, that means you come from different corners, some who have

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are normal products, i.e. those that do not fall under MDR and IVDR, but which are A.I.

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, they will probably then also primarily go this way of the 42001, which come from the medical devices, i.e. MDR, IVDR corner, they do that additionally.

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So there is not necessarily the compulsion, but there is the compulsion to have someone who can certify this product class under MDR and IVDR under the aggregated umbrella afterwards and they can do that with it.

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Exactly, exactly, with offering.

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In addition to the ISO 13485 certification, there is also ISO 42001, which has not yet been harmonized.

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But in the future, of course, the goal could be that this will be harmonized.

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Exactly, we already carry if a medical device already has machine learning aspects or A.I.

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aspects, we already lead specifically to the conventional Techtok Reviews nor specifically to the A.I.

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Aspects of Aspects Reviews in accordance with the G.C.P.R.

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17 2 in the appendix of the M.D.A.

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to cover the specific safety and performance requirements for electronic programmable systems.

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Well, we're already doing that, that's part of the C.E.M.D.A.

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contract, if we have such A.I.

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aspects in which most of the time Software as Medical Device have been included.

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We still have a certain uncertainty, everyone, we don't know yet.

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which standards will ultimately be harmonized, now of course especially for M.D.R.

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and I.V.D.

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on the one hand and for A.I.

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Act on the other hand.

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But there's just the tip, so follow us then, as soon as there is news, we will inform you about it.

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It will be a whole zoo that is currently under discussion or could be harmonized.

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Yes, how can people contact you if they have further questions or are perhaps even interested in going through the certification with you?

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Yes, just send me an e-mail.

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That's my name axinia.wolf@bsigroup.com.

00:17:26 Speaker 1

Axinia writes AXINJA dot wolf like the animal and then @bsigroup.com everything together or call me at 01754171327.

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I'll link it, preferably later in the show notes, but it's there with it.

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O.K., I'll summarize very briefly.

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Today we had the chance to talk to a representative of a notified body.

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We took a quick look at the current situation and heard the good news that this bottleneck issue has now been resolved.

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Yes, the E.U.

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about it.

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They told us what the timelines are a bit.

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Yes, that's something over a year.

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You said that of course it depends on how well prepared you are.

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And it also depends a bit on which service they book with you.

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So, you can also speed it up with money.

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We had exchanged ideas about what resources we also need on the manufacturer side in order to be well prepared for what the wishes and requirements see from their side.

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So, I would like to remind you very briefly of this English documentation, of the complete submission, of the early contact and at the end you even gave us the outlook just now that companies that are now

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A.I.

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as part of the medical device or I.V.D.s or A.I.

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are also in good hands with you as part of another product, because you are also allowed to certify according to 42001.

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Yes, Ms. Wolf, I thank you from the bottom of my heart for these insights in the direction of B.S.I. that you have given us.

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Yes, very much and thank you very much for the invitation to the podcast.