

New family of standards for autonomous cognitive AI systems

With Dr. Rasmus Adler, Dr. Henrik Putzer, 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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Here in the podcast, we have already talked several times about the use of medicinal learning of artificial intelligence in medical devices.

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At that time, it was more about topics such as, how do we use

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These libraries, do they know how to look at it legally?

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What regulatory requirements do they have to meet?

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Today we have a slightly different topic.

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Today we want to take care of an application rule that the V.D.E.

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and I have 2 guests, namely Doctor Rasmus Adler from Fraunhofer, whom some already know from a podcast on the subject of autonomous systems, and then Doctor Hendrik Putzer and both will now briefly introduce themselves so that they know.

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that we have with us in this round.

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Hendrik, let's start with you.

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Yes, of course, thank you very much for the introduction.

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Henning Putz is my name.

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I'm sitting here with several hats.

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One of them is the head of the field of competence at the Fortis research institute.

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There I am head of the Trustworthy Autonomous Systems division and

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And at the same time I am also the managing director of a consulting firm, a small consulting firm, small but nice, with the topics of processes, certainly also medical technology, but then also bringing in the technology and also A.I.

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And in this form I am also chairing this application, this application guideline of the working group, which writes this application guideline.

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This is the AK 801 08 at the DKE.

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This means that we have the absolute expert on this topic, especially on this application guideline, with us.

00:02:04 Speaker 1

That's wonderful, you're a computer scientist, if I'm correctly informed.

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Exactly, I'm a computer scientist by birth, I studied it in Braunschweig, then worked for engineers for a long time and can do both, i.e. abstract concepts and also make things work.

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Yes, on the one hand the researcher who looks at the background at Fortis and then also to bring that into industry, into practicality.

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Great, Rasmus, some already know you, but I think it would still be worth it if you introduce yourself and your role.

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and how you are connected to the topic.

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Yes, very much.

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Ja, also Erasmus Adler, mein Name.

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I am a program manager for autonomous systems.

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So, I think the reference to the application rule is clear and my background is, I've been Fraunhofer IESE in Kaiserslautern for 14 years now and have

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I have always been concerned with the topic of safety.

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Was also there for a long time in the departments and now with the role of program manager autonomous systems is a cross-sectional topic, everywhere departments.

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So, we also have a security department, engineering departments.

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Of course, these are all important topics that also play a role and I am also represented in some standardization committees, standardization committees and one of them is this A.K. that Mr. Putzer just mentioned.

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Great, so I would say, maybe we need a very first look at what is in this new document.

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And Henrik, if you could maybe give a first introduction now, that we have such a frame and maybe you could also go into it in the answer, why do we need something again now, don't we already have enough standards and then Joda has made a guideline, why do we need something here again.

00:03:54 Speaker 1

So it's a double question, so to speak, what is it about and why do we need it?

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Frame is a very good approach here, because this application guideline that we are talking about here, this application rule, is actually a framework and, if you like, it is actually not another standard formally, of course, but it is actually more of a handout on how to deal with all the complexity that affects us today in typical system development.

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We start at the very top of System of Systems development.

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We extend the aspects not only to good engineering, but also to safety security usability.

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We summarize this in the matter-term trust versiness and then we also go into technology specifics.

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Yes, maybe that we also mention the name of this, this rule.

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So if I am correctly informed, they are called the development and trustworthiness of autonomous cognitive systems.

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Yes, so if I understand correctly, machine learning can be included, but it doesn't have to be.

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Is there my, is this assumption correct?

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That is absolutely correct.

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A good point, we have the search in various places for, what is the definition of A.I.

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we squirmed around it a bit at first, but with good reason, I think we'll see later.

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We first start with the behavior of the system and see how it ultimately presents itself to all the stakeholders.

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That is why we are also affected by the term K.

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I.

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and said, these are autonomous cognitive systems, we are trying to establish this as a separate term in the end

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And A.I.

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we think, but in the end these are specific modules in the entire system design that ultimately use these new technologies A.I., machine learning, neural networks, bring advantages, bring disadvantages.

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We'll see that right away, how to weigh them up.

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So there is the system approach from above.

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comes the other name?

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O.

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K., so if I may compare this again, so to speak, with the guideline that we developed and which then also passed into the hands of the notified bodies, it is in a certain way neutral, agnostic to the specific situation, so except that it has to be medical devices, whereas your rules of application have a very clear context, systems, or more precisely, autonomous

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Systems.

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So you're a little more specific.

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Is it limited to the field of medicine or is it a domain-independent rule, so to speak, that you have brought into being?

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The application rule is actually independent of the domain and the application.

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Yes, O.

00:06:55 Speaker 1

K., that is, the domain, that is, the industry in a certain way is neutral, but what the object of consideration is very specific, namely this

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autonomous systems.

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What specific risks do you see right now with these systems, which should be addressed later?

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Yes, on a very abstract level, you can see that quite nicely in the lifecycle.

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Yes, the first risk with such systems is that, as with all other automations,

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whether there is now A.I.

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or new technologies are in it or not, the risk lies in the fact that the system is not built for the user at all and in the fact that there are ultimately technical errors during implementation.

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The risks continue to lie in the fact that the system may be sold completely wrongly, with completely false promises and ultimately may also be used incorrectly.

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So actually

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the 3 points that are considered in medical technology anyway.

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So that means that the intended use, including the users, the usage environment, does not fit with what the manufacturer actually had in mind when he built this system.

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Can you say that?

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Exactly, because and this is the big misunderstanding, now we come back to this term K.

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I., that's not as intelligent as many think.

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the A.I., which is again just an automation that works and can be used for very specific delimited cases.

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And just like in the standardizations and norms so far, this must also be clearly presented, during design, during selling, I would say now, and during use.

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Yes, we have to talk about what makes this application rule application policy better now.

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Yes, so to speak, in this consideration we could perhaps

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so that our listeners can imagine this even more precisely, give an example of such a system, which would now typically fall under this application rule.

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Would that perhaps be a question for Rasmus, for you?

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Yes, so there are different systems.

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So we had, for example, when it comes to autonomous infusions, for example, something like that.

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And if you then do it even more intelligently,

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then it would also be an autonomous cognitive system and yes, the special thing I actually see about these systems is that they can act very situation-specific and that the technologies that make this possible, behind it, for example machine learning, are now such that they are simply enormously not yet sufficiently addressed, and that's exactly what where we say in the application rule, yes, that's what the consensus is, at least

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sometimes also from the scientific side and what you do in practice to deal with it.

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Yes, and what is special is when you say, quasi I., as we see it as technology, is also software.

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Classically with software, you assume that they are systematic errors, have appropriate methods for them and exactly the question is, well, what can I do now with this new type of software, so to speak, because you just can't transfer it 1 to 1 and

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there is also the big question, are these all systematic errors or and this is becoming apparent that there are certain uncertainties, residual uncertainties and this concept of uncertainty, how is it related to risk and how can one then argue that the risk is acceptable.

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This is so that the one topic, if you really K.

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I.

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as a technology, the other thing is just the

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the systemic theme, the behavior and the new behavior that is added.

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And of course, you can also build completely new medical products that didn't even exist in the first place.

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And accordingly, there is also a bit of a lack of reference, the state of the art, so to speak.

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What is this there and do you now dare to bring this new added value that you can also have into the market with these products?

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You have to explain and explain that somehow.

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and that can be done for a security sustainability.

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You have now given us the context, could you show us with an example what a specific problem is that the application rule tries to avoid and maybe also how it does it?

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So an example of a specification in the end, I don't know, is a question more for you, Hendrik or Rasmus.

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Yes, there are several basic concepts, so a concrete example of what is very prominent there is the assurance case.

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Yes, and security arguments.

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Well, they already exist in other standards.

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But the question is, how would you set up something like that, also with regard to securing artificial intelligence and how do you argue that and what does it look like?

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That's one thing, for example.

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Or patterns are also presented.

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So, how can you actually, if you have such an A.I.

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component that measures uncertainty when it outputs something and yes, so architecture and application patterns, they are actually presented there.

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Nendrik, maybe very briefly that we have another example of what caused this problem, so to speak, where these rules of application help, for example through these specific specifications, as Rasmus just mentioned to us.

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Yes, there are many prominent examples in medicine that are being discussed at the moment.

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As I said, our rule of application is independent.

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I wouldn't say now that we can only or must focus on one category with the application rule

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But to put it vividly, when we have a medical robot, what do I know, OP 4.0, which really performs operations autonomously, then you always ask yourself, where are the limits, where exactly does the human still have to intervene or, more concretely, at the top level, what are the responsibilities of the robot,

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with K.

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I.

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as intelligent as he may be, he has limits and where is the demarcation exactly from the surgeon, who also has to take on certain responsibilities, what exactly is the division of tasks and how are the handovers and this clear separation, that is the special feature of our application rule, which runs down across all system levels, by designing these autonomous cognitive systems, as we call them, and saying exactly,

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If I have risks now, where do I have to allocate them, to which element, to which functional strand of the chain of effects in my system implementation?

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Where do I have the risks?

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And if they are waiting for an A.I.

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fall when an A.I.

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element in this strand of action,

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how do I have to build them exactly, so that I can provide these guarantees that I have to provide for this chain of effects and for the safety and effectiveness at this point, in the safety argumentation, how do I do that?

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So methods, measures and then of course on the higher levels again such design patterns, how do I build something like that

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Redundancies, depending on what you need for features.

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And then you give very concrete examples that you should use, so they are demanded or are they rather things that you find in the appendix, for example, as suggestions, so you can do it.

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So the background of my question is actually, how specific is this application rule?

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Mhm, as I said, it's never specific to an industry, so we can't be exactly there.

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But what you see here is that these new technologies, machine learning, neural networks, they have similar problems in all industries.

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What we would like to see is that we all know the 61508, which assumes this safety integrity level and the methods are graded depending on the integrity requirement.

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No, we are not there yet.

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Research is not yet so far along and it would be dubious to make a standard at this level now.

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I assume that this may be in version 2 or 3.0.

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We have actually, as you say, Christian, put something like this in the attachment as an aid.

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If I take the system design, for example.

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Is there an appendix that clearly says, what design patterns do I have with redundancies, with monitor functions or with online verifications, how can I use this to ultimately use such system architecture or mini-architectures for an overall security argument?

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Mhm, you have already given some examples, so what was demanded or

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is perhaps more likely to be proposed.

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The Design Patterns were an example of this.

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Perhaps we can take another look at a concrete application procedure now.

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I would find the one you wrote with the O.P.

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Robots very vividly and now it could be, for example, that the way an algorithm, a model has been trained, leads to a situation that is now being used in the concrete O.P.

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scenario of the robots is not compatible with

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Yes, because he may not yet receive exactly this data or this set of input data in this form and is now dealing with it incorrectly.

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In other words, it ultimately makes a decision that is not appropriate to the situation.

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Where does this guide come in?

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So it starts very early, for example, how does such a model have to be trained or does it take the place, how do I have to deal with risks that arise from such an incorrectly trained model?

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Mhm,

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It's funny that you say early on dates, for us, it's extremely late.

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We start much earlier.

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We really look at this procedure, this this process of the intervention ultimately and look at where risks can arise.

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Let's take a knee operation, that suddenly the ligaments are just in the way and or some vessels

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And now you have to identify the risks from this abstract level and bring them down to the A.I.

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ultimately draw the requirements, the normal traceability, which we have always demanded, regardless of the technology, ultimately say, what does the A.I.

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take into account.

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Yes, it simply has to recognize when the situation is abnormal or when there is a critical point,

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that this must then ultimately lead either to special treatment or to the involvement of the surgeon himself.

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And then, now you said, early data, then we would first get to the data and say, well, we now have a description of this domain in which we work.

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and say, O.

00:18:12 Speaker 2

K., what can happen there and then we make an operationalization of the domain, so to speak.

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We say, what has to be recognized, what kind of tissue, what kind of complications can occur and then we say that it has to be represented in a data set.

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Yes, that's what there is again, then we really go in, we have special phases for it, it's called data preparation,

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who then says, O.

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K., what kind of samples do I need, how do they have to be distributed.

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On this domain, if you formalize it sufficiently, you can also say how dense my data is, what kind of domain coverage do I have in my data.

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There are actually metrics for this and they are also suggested.

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I hear that it is ultimately a fault tree analysis approach that we can use very early on.

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and then shimmy down from the intended purpose, so to speak, along the architecture and then always look at the respective level to see what the measures that need to be taken.

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This means that you use risk management, as it should be, not only as a checking element at the end, but as an important method to generate design inputs.

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Can you say that?

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Yes, you can definitely say that.

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the basic idea is there and what I find very nice, just this connection to the new technology below and

also consideration of risk, risk assessments, what you can do with this new technology, as a new behavior.

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Yes, and finding the balance right there, that's one thing.

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Another thing is that what plays into it are topics that you can

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new or new hedging issues, for example, that you no longer always work with worst-case assumptions.

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Yes, we already had that in the other podcast where I mentioned it, on the one hand you have the risk that it presents itself differently because the context changes.

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It depends on the situation and it is precisely this situation that you can recognize and accordingly you can act differently and behave intelligently.

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And for this, too, concepts and basic ideas are described there, for example.

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like that, how you can build something like that and get it done.

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Yes, and of course this application rule differs from the guideline, for example, because you have just built up a framework that is now specifically aimed at this system, these autonomous systems, and then looks completely over the life cycle, what has to be done in each case and what are the corresponding best practices.

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How far have you come with that?

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Has it already been published or what are there

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is that the roadmap, the timeline that you expect?

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You know it from Softwarekern, I'm a computer scientist, they're always ready right away.

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Yes, tomorrow.

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No, joking aside, the application rule is divided into several parts.

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Strictly speaking, we have 6 core parts that deal with basic concepts

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and with what we call the solution level, i.e. what is above the system, deals with all stakeholders in the environment.

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The two parts are already available via the V.

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en.

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Below that would be the system and the technology level.

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System is exactly this level that now says, I have design patterns for verifications, i.e. redundancies, monitoring and so on.

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Or specific AI functionalities such as continuous learning or something like that, what do you have to consider?

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This volume and the Technology Level, where it's really about the properties of convolutional neural networks or deep reinforcement learning or those technologies that are used in the future.

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And the band that says, ,Okay, what do I have to do

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after production, when I have brought it to market, so when I have it, when the development is finished, also this, this Kappa process in the end, which then also follows it, that is already available.

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What is still planned, but which we have postponed for the time being, are guidelines on how to apply them in concrete terms.

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You actually always live better in examples,

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that's a bit backwards, but all but 2 of the core parts are available.

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That is, you would recommend that medical device manufacturers use it in order to ensure conformity with the requirements of the M.D.R.

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or in U.S.A.

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with the F.D.A.

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Then to fulfill or definitely yes is the rule of application

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not yet in the sense of a harmonized norm, we are far from that.

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Yes, what is a rule of application, that is the lowest binding form in Germany at least, but that is only the legal side.

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I think the thing that needs to be emphasized for the application rule is that in this form, even if several working groups are now working on something like this, it can be done at ISO level at the I.E.C.

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and so on,

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this is now the first available form that a framework in this form ever provides.

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And of course, it is correct, as a presumption, that you go through it and say, I might take it as a checklist, yes, for existing products, to be sure, I have thought of everything.

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I might actually take it as a guideline for new development,

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So, the applications are very broad.

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Mhm, yes, I think that we are reflecting the state of the art.

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We are currently very successful with harmonized standards, but somehow they can't get them right.

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That means you will certainly have to look at the thing.

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Now we have just learned that there are now several volumes that have to be taken care of.

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That may be a tough task for someone who is new to the team.

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How could you help you to understand and implement these rules of application, which are probably more likely to be several?

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What should our listeners do if they feel they need support?

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Yes, of course they are very welcome to contact us and we are also really looking with the consortium to say we really want a consistent example.

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It just heard that such a guideline should also be written

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And of course, it is perhaps even suitable to have several examples to see how this is applied in this or that case, because it is also goal-based due to the breadth, it has to be.

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No, so she doesn't prescribe much and says that it has to be that way in any case, because if you have that in mind without the concrete example, then you might prescribe something that is not necessary in a specific case.

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That means it's more like you say you have to think about it and definitely look at it.

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whether it shouldn't be used sensibly and that's why it has such a character that you can go through it.

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Yes, and that's definitely an important next step.

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Yes, if I may add briefly, we are of course happy to give such an introduction to this standard at that time.

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In any case, I would advise not to be deterred, yes, to be frightened by all this content.

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That may be many volumes and many pages, but

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But the decisive thing is what Rasmus just said, we went in with objectives, i.e. goals, and if you meet them, yes, then you have ultimately fulfilled the state of the art in the sense of implementation.

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The rule of application does not prescribe any cooking recipes, but says what you have to think about.

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I think we are in the A.I.

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and in complex system development, systems engineering, not to the point where you can say, you don't do it this way and that way if you are independent of the industry.

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But what you have to think about and what the pitfalls are, it's somehow the same thing over and over again, no matter what industry I'm in.

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You have the complex technology, you have the people and you have regulation.

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Yes, and we try to give a way and

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I would like to give that to all listeners.

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This is not another standard that somehow gives us an ankle bracelet and makes us move even slower, but this is a collection of best practices that you can use for yourself.

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Yes, and actually turns the ankle bracelet into a skateboard, with which you can then move faster.

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I think that's a wonderful final word.

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Yes, that means that all those who want to learn skateboarding even faster right now can turn to Henrik and Rasmus.

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And I heard it between the numbers, that can also be a real win-win situation.

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On the one hand, the two can help, but on the other hand, as a listener, you can perhaps also contribute with practical examples, so that the next version of this guideline can also help future readers even better, because it is then even more vivid.

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Yes.

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And so we hope that we will bring all the people together.

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That's why I will also be mentioned in the show notes or

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publish the contact details of the two in the article below, so that they can then get in touch with them directly and we can then skateboard together.

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Dear Hendrik, Rasmus, that was wonderful.

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Thank you for your time.

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Yes, thank you.

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Yes, thank you very much.

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It was fun.