The EU AI Act in Focus: Making Sense of Conformity Assessments Transcript

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Bas Overtoom: Good morning, everybody. Welcome to this webinar on the EU AI act, making sense of conformity assessments. Very happy to have you here, and we look forward to an interesting webinar with you.

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Bas Overtoom: So my name is Bas Overtoom. I'm the Global Business Development Director of Nemko. Digital I'm here, together with my colleague Monica will bring you through the Euai Act and the conformity assessment, and explain all the details that you need to know as an executive to go through the

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Bas Overtoom: the regulations that are coming up.

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Bas Overtoom: So maybe the next slide, Monica Namco digital.

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Bas Overtoom: we are a company from Nemko Group. So Nemko group is an famous product, compliance tick player, active around the world with 90 years of history, helping companies to make product compliance

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Bas Overtoom: work and global market access all over the world. And since 2 years we are also focused on the AI topic. And since last year we have the Nemko digital brand based out of Amsterdam to help you with all your AI embedded in products, and also give advisory on AI to make sure you develop and deploy it in the best way possible.

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Bas Overtoom: So that is a bit on Nemko. Maybe the next slide. This is us, and I have introduced myself also on Monica will introduce herself a little bit further on. If you go to the next slide, you see some of the key things that our clients are focused on as Nemko. We basically do 2 things. It's good for you to understand. So one is that we help within product. As I already mentioned.

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Bas Overtoom: we have a global recognized trust. Mark that we bring now all over the world to our clients, and also to new clients that want to show to their customers and stakeholders that their products are trustworthy. When it comes to AI, we do a lot on helping organizations with AI, that is, implementations of Iso, 42,000 AI management systems. We have a maturity model.

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Bas Overtoom: We help with tools and technologies to implement to organize data governance. And we do data literacy. And then the last is that we also give a lot of advice on

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Bas Overtoom: regulations when it comes to AI, as Monica will explain to you in more detail. Probably there is a lot of regulations coming up all over the world. And as Nemko digital, we're monitoring all these regulations, and also some of the differences between those regulations, and also some of the overlap and the similarities.

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Bas Overtoom: Today, we focus on one of the most prominent regulations of that. That's the Euai Act, which is also a base, for many of the regulations are inspired by the Euai Act.

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Bas Overtoom: We've done a couple of webinars on the Ui Act, and we got from you a lot of requests on this conformity assessment. And how this exactly is gonna work and what this exactly means. So that's why we deep dive with you today onto the conformity assessment. So with that, I give it to my colleague, Monica, to take you away into this topic.

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Monica Fernandez: Thank you. Pas? I'll do a short introduction of myself. I'm Monica. I'm the head of AI assurance at Nemko, digital and I help shape and deliver services around AI Trust. I have a background in neuroscience. And AI and I've worked across research, education and policy which

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Monica Fernandez: made it so that over the years I've become quite familiar with the AI act. And this is why I'm here today. So I'm gonna help you navigate conformity assessments and understand what they mean for your AI systems.

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Monica Fernandez: So without further ado, we'll jump into the EU AI act.

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Monica Fernandez: So the EU AI act is now enforced. It's setting a unified regulatory framework across all of Europe. And the most important thing to understand about the act is that it follows a risk-based approach.

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Monica Fernandez: It also has strict requirements mainly for high risk AI systems and clear rules and transparency, and of course, like with any regulations, there are tough penalties to to consider with noncompliance. It was adopted last summer in 2024, and it will become fully enforced by 2026. So it is time to get ready.

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Monica Fernandez: Now here is the EU AI act at a glance. Like, I said. It follows a risk based approach, which means that AI systems are categorized by risk ranging from prohibited to low risk AI systems, and they even place general purpose AI into its own category.

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Monica Fernandez: And this chart we can see who is responsible for what we can see, that for high risk. AI, all actors, so providers, deployers, importers, and distributors, have obligations and must undergo a conformity, assessment.

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Monica Fernandez: limited risk. AI meet trans. Have to meet transparency requirements while low risk AI face no obligations, but they are, of course, more than welcome to follow general codes of conduct. And then, last, but not least, there's general purpose. AI, that falls into in

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Monica Fernandez: into its own set of rules. Given the their nature.

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Monica Fernandez: Now we've seen how the AI act assigns obligations based on risk. But we have to stay. Take one step back sometimes and discuss what actually counts as an AI system under under the act.

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Monica Fernandez: So the definition is intentionally broad. It covers any machine based system that can operate with some autonomy that can adapt after deployment and that can generate outputs like predictions, contents or decisions

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Monica Fernandez: based on input that it receives. Now, this includes Standalone, AI software, AI built into physical products, or even AI that's connected to a product without being a part of it. So if it's like a safety component of a of a product.

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Monica Fernandez: It also covers AI, that is just one part of a much larger system as well.

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Monica Fernandez: So examples of AI systems will be a recommendation algorithm in an online store facial recognition system or an AI that is embedded in in an air conditioner and can adjust temperature based on user behavior

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Monica Fernandez: and examples of what is not an AI system are simple rule, based thermostats, or a spreadsheet with formulas or hard coded scripts, with no learning or adaptability.

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Monica Fernandez: So all in all. If your system learns, adapts, and generate updates, chances are that it is in scope.

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Monica Fernandez: So what exactly counts as high risk under the AI act. There are 2 main categories. The 1st one is AI systems that are part of or contribute to the safety of physical products, like cars, medical devices, or machinery, these products that are already regulated by EU law.

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Monica Fernandez: If these products require a 3rd party conformity assessment, and your AI is part of that product, it's considered high risk.

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Monica Fernandez: Now, second, on the other hand, we have standalone AI systems that can be high risk if they're used in sensitive areas like in education, employment, law enforcement or access to essential services. These areas are listed under annex 3 of the AI Act.

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Monica Fernandez: and these systems must be registered in the EU database, and meet also the strict requirements that come along as obligations for high risk air systems.

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Monica Fernandez: However, in short, if your AI affects safety or fundamental rights it, it does likely fall under high risk.

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Monica Fernandez: So now we have a question to you. I'll give you the word. Pass.

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Bas Overtoom: Yeah.

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Monica Fernandez: Good.

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Bas Overtoom: Thank you. And so the the question we just have the 4 levels of risk that you saw. And the key question is.

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Bas Overtoom: Are you aware of your AI systems and into risk

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Bas Overtoom: level they fall. And I think, as it is good, you will get a pop up

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Bas Overtoom: that it's coming. And basically, we ask you all to fill it in. And then, if possible, we look at some of the direct answers, and else we do that later. So, yes, we have already categorized our systems, or we have a general idea or not. Or, yeah, I was actually not aware of them, actually that there was this risk categorization. So this is also when we're looking at the 1st step, when you want to start to confirm to the Euai act

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Bas Overtoom: getting this risk. Categorization organized is basically the 1st key step to know what you need to do.

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Bas Overtoom: So if people are filling it in, I think it will take a bit of time, I think. Later on, Monica, you can continue now, and later on we will see to some of when we come to the Q. And a. We will see a little bit also what some of the answers have been.

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Bas Overtoom: for now please fill in the poll, and we'll continue with the conformity assessment. And then in the end, we'll review some of the results of your of this poll, Monica.

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Monica Fernandez: All right. So moving on to conformity assessments

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Monica Fernandez: now for the 1st time Ce. Marking now applies to AI, and this means that under the AI Act any high risk, a system must pass a conformity assessment before it can be ce marked. This shows that it meets all the necessary requirements that one must meet

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Monica Fernandez: and the Ce marking can be both digital and physical. So in a digital sense, for systems accessed online or via code and for physical, for mainly AI embedded in in products. Often both can be used together.

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Monica Fernandez: and according to Article 48 of the AI Act providers are responsible for affixing the Ce. Mark to prove the main 2 things, which is one, that the AI system is in compliance with the act, and 2, that the AI system can circulate freely in the EU market.

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Monica Fernandez: So who actually needs to carry out a conformity assessment? Well, that hugely depends on your role. Providers have the clearest responsibility. If you're putting a higher risk system on the market or into service, you need to do the assessment, but it doesn't stop there, because, as you can see distributors, importers, deployers, and other 3rd parties might also trigger this obligation.

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Monica Fernandez: especially if they put their name in in the system, or make any significant changes, or shift its intended use in a way that it does become a high risk, even though initially, if the system wasn't high risk, this could trigger that they have to do the conformity assessment themselves.

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Monica Fernandez: and finally, for product manufacturers. If your AI is a safety component of a product or part of a product in itself that is already regulated by EU law, like medical devices or toys. You need to ensure conformity under those rules, too.

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Monica Fernandez: So

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Monica Fernandez: just as a reminder. If the system changes in any way that it affects its compliance or purpose or intended use, you need to reassess

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Monica Fernandez: now. We talked about roles, but roles do get a little bit complicated when we're talking about general purpose. AI

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Monica Fernandez: especially when they're being developed by 3rd parties. So

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Monica Fernandez: this image. This flowchart is easier to visualize what happens in terms of roles.

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Monica Fernandez: and how it depends on the level of integration. And how it's used. So here at the top we have vendor, one who creates a general purpose. AI model and hands it off to vendor 2.

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Monica Fernandez: This vendor integrates it into a full AI system. So what does this mean? This means that both are considered providers right now, vendor, one is a provider of general purpose. AI and vendor 2 is a provider of the high risk. AI. If if we're talking about a general purpose, AI that is integrated into a system that is high risk

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Monica Fernandez: now depending on how it's used. Customer, a, as we can see, could either simply use the system for internal purposes and therefore become a deployer

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Monica Fernandez: or build something new on top of it, making them a provider as well.

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Monica Fernandez: And then there's Customer B, who just uses the final system and is therefore clearly a deploy.

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Monica Fernandez: So the key takeaway of this is that your role and your responsibilities can shift, depending on how deeply you integrate or modify the AI system, and how you use it.

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Monica Fernandez: Now, 2 types of conformity assessments we need to take into account when we talk about about them.

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Monica Fernandez: So let's look at the 1st type. It's internal control.

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Monica Fernandez: This is essentially a self assessment that can be done without a notified body. If the provider follows harmonized EU safety standards. That's why this route is most commonly used by, or will become the most commonly used by providers.

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Monica Fernandez: However, what does it involve? So first, st you need to show that your quality management system meets the Aix requirements. This includes things like

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Monica Fernandez: regulatory compliance, technical specs, testing data management and risk monitoring.

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Monica Fernandez: You also need to ensure that your technical documentation shows how your AI system meets all relevant requirements, especially around its design and the development. And how are you implementing any post market monitoring.

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Monica Fernandez: Once everything is in place, you'll have to prepare a declaration of conformity

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Monica Fernandez: you'll have to commit to keeping the documentation for 10 years, and finally, you can fix this earmark to the products so it can circulate across the EU.

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Monica Fernandez: This is a very structured but very manageable process. As long as your system stays within the scope of harmonized standards.

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Monica Fernandez: Okay.

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Monica Fernandez: now, the second type of conformity assessment is, it requires more involvement, of course, because it requires a notified body. This applies when you can't really rely on harmonized standards, and in this case a notified body steps in to assess your quality management system and technical documentation.

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Monica Fernandez: They can handle the testing certification inspections, everything that's included in the internal assessment. But more

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Monica Fernandez: now, with this, we need to take into account that notifies parties can get full access to your training, validation and testing data sets. They can even request access to your trained models if needed.

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Monica Fernandez: and they also have the right to inspect your premises where the development design or testing of the AI system happens, and to carry out regular audits to make sure that the quality system is still up to standard.

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Monica Fernandez: And yeah, in some cases they may also conduct additional testing to verify compliance before issuing any, any certification. So if you're not relying on harmonized standard. There's a more rigorous but necessary path to market.

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Monica Fernandez: So how do you know which conformity assessment route applies to your as system? It depends on, first, st the type of as system, second, the sector that is used in, and 3, rd whether the harmonized standards are available.

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Monica Fernandez: So let's let's walk you through some of the routes

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Monica Fernandez: 1st here on the left. If you, if your AI is embedded in products covered by the new legislative framework like medical devices, toys, or radios. This means that it falls under annex one section A of the AI act.

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Monica Fernandez: Now, if this sector allows for opt out from 3rd party assessments, using harmonized standards or any other common specifications, and those standards are available and applicable.

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Monica Fernandez: You can follow the internal control route. But if not, you'll need a notified body assessment

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Monica Fernandez: for AI in products not covered by the new legislative framework like vehicles, trains, and planes, and those are the ones under annex. One section B of the AI act. The act only applies partially until at least until sector specific laws adopt AI rules. This has to be monitored in detail.

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Monica Fernandez: If your AI is used in critical areas like infrastructure, education or employment, the ones that we mentioned earlier in in the webinar, this means that it falls under annex 3 and can typically follow internal control. Assuming that harmonized standards are available and use.

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Monica Fernandez: Last but not least, biometric systems, like facial recognition or emotion, detection fall under, annex 3 as well, but only under the 1st point, and the act specifically says that if harmonized standards are applied internal control is possible, however, otherwise it's a notified body assessment that it has to go through.

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Monica Fernandez: In short, your route depends on the product category, the applicable laws, and whether harmonized standards are in place.

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Monica Fernandez: Now here we have the EU AI at timeline. I've showed this timeline before at previous webinars. There's quite a bit of information in here. You can take your time to to look through which dates certain obligations apply.

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Monica Fernandez: But something to point out based on. What we just talked about is that, as you can see. In August of this year of August 2025

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Monica Fernandez: national regulatory bodies will be appointed, which means only then they can start the process of designating these notified bodies.

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Monica Fernandez: In the meantime harmonized standards are still not published, and they will not be published until probably the end of this year.

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Monica Fernandez: So what does this mean if we cannot make use of them for internal controls, and we cannot go through company assessments with a notified body.

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Monica Fernandez: Well, providers are starting to prepare regardless and collaborating with parties like us, they are preparing their quality management systems. For example, they are getting their technical documentation in order. They're following draft versions of harmonized standards or or Iso standards that are equivalent

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Monica Fernandez: or where where possible applicable. And then also monitoring common specifications, developments from the European Commission.

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Monica Fernandez: Now, I've said a lot of things. A lot. The last thing I said are the things that providers are doing today more long term. And they're already they've already started these more extensive processes.

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Monica Fernandez: But what I like to to say, or what I. The way I like to break things down. For people who are just entering or thinking about the AI Act is to think about step 0. So what is step 0 step 0 means that what you have to do today is understand your use case. So

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Monica Fernandez: this means asking yourself these 5 key questions. 1st of all, are you dealing with an AI system under the Aix definition like we, we walked you through earlier in the webinar? If so, is it considered high risk?

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Monica Fernandez: What is your role? Especially if you're using or integrating general purpose? AI from 3rd parties.

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Monica Fernandez: and which conformity, assessment route applies to you. So in terms of which conformity, assessment route can you take? What is the state of product regulations?

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Monica Fernandez: And harmonize standards in this moment? And finally, what steps would you need to take to drop your declaration of conformity when the time comes?

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Monica Fernandez: Now these are a lot of questions, especially with all the things that you can do after step 0. It can be very daunting for a lot of companies and organizations. So what we've done at Namco digital. We have this process. We've developed that basically merges all of these steps into one singular process. And in the end it even gives you what we call an AI trustmark.

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Monica Fernandez: So like I said, our AI trustmark helps you answer all these key questions, using a risk-based approach that aligns your AI systems with with the relevant regulatory requirements, including those of the AI Act.

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Monica Fernandez: It includes our risk categorization methodology, which I will show you show you some of in the next slide

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Monica Fernandez: in a way, so that it can help you understand how your system will be viewed from a compliance standpoint, or how is it view under the AI Act?

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Monica Fernandez: But this mark isn't just about ticking boxes. It's about also building trust. So while you're going through this process, not only are you ticking boxes, but you're also showing your clients and your partners that your AI is transparent. It's reliable. And, most importantly, know, it's aligned with regulations. And this way you can boost user confidence and market credibility.

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Monica Fernandez: So yeah, if you're ready to move from from planning, from thinking about what you need to do into actually acting on it. Then the trust mark is the way to to get you there.

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Monica Fernandez: Now, this is the process that we take for our risk categorization. We've done this with several clients already. Where? They've asked for a small EU AI act awareness section set session and then would go and dive into an in-house consultation on the AI system, followed by providing them a product questionnaire. And then, with the the answers given, we can do

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Monica Fernandez: a risk categorization against the criteria of the Eua Act and the main deliverable of this.

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Monica Fernandez: an evaluation report that comes along with recommendations, an evaluation statement.

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Monica Fernandez: So it's been a lot of information. But of course, we're open to questions. I'll give the words to to bass now. And yeah, you can ask any questions.

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Bas Overtoom: Yeah, you can ask some questions in the chat, and while you're typing away your questions I will give some small updates, and then also, we'll share the results of the poll. Maybe if you go to the next slide. Monica. There, you see. Yeah, just we have some other other webinars coming up also. So one on the trust mark in the end of June, and the next one is a literacy. So please follow us also on Linkedin. If you go to the next slide.

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Bas Overtoom: then you will learn all about this things that are happening, and we also provide a lot of knowledge there on Linkedin. So it's not only the Euai act, but all these other regulations that are coming will provide input and output and practical things like you just saw the sheets from Monica on how to evaluate where you are in this journey. It's either a deployer or a provider, etc, etc.

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Bas Overtoom: If you go to the next slide. Then? It is basically giving you. We basically want to give you this opportunity. If you've joined. And we had the results just now from the poll. And the results are that we saw that there's only 3% of the people that is out there. You're almost 200 people here

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Bas Overtoom: that said, we have already categorized our system. So most of you haven't categorized it. But more than the majority. So 56% says, we have a very, we have a general idea where we fall into the thing. So that means you have also done some

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Bas Overtoom: homework. There's another 26% that is planning to start categorizing them. And there's also a few people that said, Hey, I didn't have any idea. And we have no idea how to start quatical racing them. So that's basically where we are in the journey. So the majority has a good idea. But yeah, almost 95% hasn't formally done it. So for all that, 95%, we have a great offer.

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Bas Overtoom: And that is that this risk categorization process, which is a small project. Normally, we do that for around €6,000 for everybody that is interested to do it. You can register here for a voucher, and that voucher means that you can get it for 50% discount.

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Bas Overtoom: we can help you to formally categorize this risk. This voucher is valid for 3 months. So if you fill in your names and details, and you start a project with us, for within 3 months we give you this opportunity. It's only for the people that are here now in this webinar. So yeah, if you want to make this step, and you want us to make it. Now

then, please sign up for this promotion. Then let's go into some of the questions that are coming in.

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Bas Overtoom: and when picking into it. Maybe the 1st question is about this timeline?

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Bas Overtoom: So in the timeline Monica, we see that some of things are quite, quite far away. But what do you think that the time is needed to be able to prepare for such a kind of conformity assessment. So yeah, what would be your your advice in that.

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Monica Fernandez: Well, it largely depends on mainly that it always depends on the use case on the type of AI, on whether it's multiple AI that you wanna put to the same conformity assessment and also depending on

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Monica Fernandez: the organizational structure. So if your company has good AI governance and you can collect all the documentation that is necessary. Put it in place, in a in a timely manner. Then it would obviously be a shorter time period that you need for the conformity assessment. But I would say in general.

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Monica Fernandez: a few weeks, perhaps like 6, it really depends on on

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00:28:51.770 --> 00:29:06.820

Monica Fernandez: on the company and and the use case. And if it's a high risk with the general purpose AI integrated in it, or if it's a high risk embedded in a product, or if it's a standalone, high risk. AI.

122

00:29:06.950 --> 00:29:13.260

Monica Fernandez: Those factors are involved in determining the the length of of the confirmation.

123

00:29:13.260 --> 00:29:24.190

Bas Overtoom: That's clear. That's clear. Yeah, it really depends, indeed, how much to add a bit, how much you already have in place. So if you have Iso 42,001, or you have strong data governance

124

00:29:24.770 --> 00:29:48.439

Bas Overtoom: in place, then yeah, then things might be simpler. But yeah, if you are lower in the maturity. Then maybe it's good to take a lot of time to get started. Better to start early and know that you don't have to do too much. Then wait for the deadline, as we see, often happen actually at some of our clients, and then there is no consultants and support available, or everything is premium priced.

125

00:29:48.580 --> 00:29:55.449

Bas Overtoom: So now is the time to get prepared, and you can also enjoy a more robust.

126

00:29:55.810 --> 00:30:05.204

Bas Overtoom: let's say, organization that can also develop AI in a better way, maybe another question here from the audience. It is about deployers and

127

00:30:05.800 --> 00:30:18.060

Bas Overtoom: providers. So they both need to do the conformity assessment. How does that work? Monica? That's the question. Is it different? Because they are both think in the slide. But.

128

00:30:18.280 --> 00:30:24.790

Monica Fernandez: No, mostly providers have to do the conformity assessment if it's necessary. In the 1st place.

129

00:30:25.230 --> 00:30:49.757

Monica Fernandez: the employers, the obligations that deployers tend to have is making sure that they have the information necessary from the provider. So this includes making sure that the provider does indeed have a confirmity assessment, getting all the information that is necessary on top of all the other obligations that deployers have which tend to be more about transparency and

130

00:30:50.180 --> 00:30:55.380

Monica Fernandez: and monitoring and risk management from a deployer's point of view.

131

00:30:56.530 --> 00:31:00.618

Bas Overtoom: So a last question also, considering the time,

132

00:31:01.590 --> 00:31:08.011

Bas Overtoom: doesn't mean that there, do I understand correctly? Somebody asks that I don't understand the

133

00:31:08.650 --> 00:31:23.170

Bas Overtoom: that I understand. Sorry that there's no notified bodies assigned yet. And how does that work? What to do and how to get going? And and how do I know what to do? And this is somebody that is focused on medical devices.

134

00:31:25.320 --> 00:31:43.263

Monica Fernandez: So there is no notified bodies for AI to look through the provisions of the the AI act. Yet no, that is the case we are hoping, or we're assuming, that towards the end of the year, the second half of this year these will be assigned.

135

00:31:43.750 --> 00:31:58.829

Monica Fernandez: of course, what what you can do in the meantime, is everything we talked about earlier in this slide, so you can already start working internally, or with 3rd parties like us to make sure that the Commun, the documentation is in place

136

00:31:59.220 --> 00:32:25.850

Monica Fernandez: for certain sectors like the medical sector. Since the regulations in the medical sector. So the Mdr. Does account for for AI and software those aspects that are dealt with in the Mdr. Those processes are already in place, and there are notified bodies for that as they were before the AI act, even came into place.

137

00:32:25.850 --> 00:32:38.699

Monica Fernandez: So the under the in in the medical sector some AI features are being regulated right now, for sure, by notified body, simply because they already fall under the Mdr.

138

00:32:39.610 --> 00:32:53.889

Bas Overtoom: Thank you, Monica. And considering the time we have to round off this, there is the email address here that you can reach out or our website for further questions. If you want to deep dive on one of the aspects, or you want to kind of

139

00:32:53.940 --> 00:33:14.230

Bas Overtoom: understand better how the Mdr. Works versus the Euai Act. We didn't really even speak about all the other regulations. That's unfortunately I had myself a question for you, Monica, but I had to prioritize the questions of the audience like, How does that work? If you are exporting to, let's say, 100 markets, how do you make sense of that

140

00:33:14.340 --> 00:33:39.689

Bas Overtoom: that would be also interesting. We will maybe touch upon that later. In one of the other webinars. Please follow us as Linkedin, and stay on top of what's happening. And I said, if you're interesting to start your AI journey to comply with the Uai Act, make use of our offer to do the risk categorization project for your AI algorithms.

141

00:33:39.860 --> 00:33:52.340

Bas Overtoom: Thank you very much. The slides and the playback will be available in our website. You will get an email, and then you can download the slides and make use of it.

142

00:33:52.840 --> 00:33:56.860

Bas Overtoom: so thank you all, and wish you a great day.