Mastering EU GPSR Compliance for Digital & AI Products - Webinar Transcript

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Bas Overtoom: Hello, everybody, and welcome to yet another webinar of Nemco Digital. I'm Baz Overtome, I'm here together with my colleague Monica, and today we're going to speak with you about

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00:00:20.040 --> 00:00:36.469
Bas Overtoom: the general product safety regulation, and specifically the AI and digital elements that you need to be aware of when bringing consumer products to market. So you will learn all about what the regulation entails, and what you need to do to comply.

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Bas Overtoom: So, yeah, without further ado, let's dive into it. So, yeah, already mentioned myself, Global Business Development Director of Nemco, long experience in data analytics, and now bringing that to market to help scale out trusted AI across the globe.

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Bas Overtoom: And maybe, Monica, you can say a few words about yourself.

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Mónica Fernández Peñalver: Yeah, so I'm head of AI Assurance at Nemco Digital, AI Trust expert.

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Mónica Fernández Peñalver: been involved, for quite some years now in projects related to AI regulation and AI policy, so I'm bringing my expertise into the team in order to provide, the services that, we are providing today regarding digital trust and AI trust at Nemco Digital.

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Bas Overtoom: Great, now.

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Bas Overtoom: let's go into the content and bring you along. This is a bit of the history of the company. Nemco has a long history of 90 years in product compliance, and now from an Amsterdam base, we are leading the AI Global Competence Center, and from that location, we're bringing you also this webinar.

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00:01:47.300 --> 00:01:48.450
Bas Overtoom: Next page.

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00:01:49.070 --> 00:02:07.390
Bas Overtoom: Some of the key elements that we are doing, of course, a lot of regulatory compliance, as also the general product safety regulation that we will dive into, also getting organizations ready with ISO certification, global market access, with all the safety standards for your products that contain AI.

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00:02:07.390 --> 00:02:12.460
Bas Overtoom: We have a Nemco Trustmark that you might have known and learned about in other webinars.

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00:02:12.560 --> 00:02:29.830
Bas Overtoom: And on the other side, next to the compliance service, we're also doing, yeah, let's say, advisory services. So we are really, let's say, an expert company when it comes to AI trust and implementing that at scale at larger and medium-sized organizations.

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Bas Overtoom: Maybe the next slide?

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Bas Overtoom: So, today, we will talk what I already said about the General Product Safety Regulation. So, most of you might have heard about the General Product Safety Declaration that was transferred to the regulation to make it more harmonized across Europe last year, 2024 by the end of the year. But also, next to that, it also started to include some of the

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00:02:57.920 --> 00:03:13.199
Bas Overtoom: new requirements on data, and especially AI, and that is specifically the point that we want to point out towards to you in this webinar, because not everybody is aware of it, but it has already been effective now for 12 months.

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00:03:13.380 --> 00:03:25.859
Bas Overtoom: And it is of essential need that you comply with these elements if you bring consumer products with digital elements to the market. And we see in our client space that some people are overlooking this.

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00:03:26.030 --> 00:03:42.040
Bas Overtoom: this, so hence we want to bring this to the attention. So we will dive into the differences, what happened, the exact timeline, given a little bit of an example of what we mean with it, and then really go more into, yeah, how the GDPR is

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00:03:42.840 --> 00:03:53.709
Bas Overtoom: positioned as a catch-all regulation. Monica will dive into that, what we mean with that, and we want to spend a bit of time on the interaction with the EUAI Act, because

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00:03:53.710 --> 00:04:02.769
Bas Overtoom: when it comes to AI and AI and products, I think we see that most companies, they are busy with the EUAI Act, but yet that act is,

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00:04:02.770 --> 00:04:26.369
Bas Overtoom: not fully enforced, might be even delayed a little bit. We will speak also to that in this webinar. And it is risk-based approach, and in that approach, you will also see that, yeah,

maybe if it's low-risk AI, then you do not need to do anything, or very limited requirements. But that doesn't exclude you from the things that we will talk about with the general product safety regulations when it comes to consumer products.

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Bas Overtoom: So, because there's so much talk and emphasis, and as you will probably see on LinkedIn or any other platform, everybody's talking about the AI Act, but not so much people are talking about these important regulations. And to really make clear what and how they are working together, and how this

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00:04:41.400 --> 00:04:55.579
Bas Overtoom: interlinked, we will spend a bit of time there to clarify that, because we see that there is quite some, let's say, either unawareness or sometimes confusement in the market and when we speak to our clients and partners. So.

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00:04:55.580 --> 00:05:07.819
Bas Overtoom: That's basically the beginning, outlining the law, this interaction, and then we just quickly explain to you in very clear terms what do you then need to do exactly to comply, and how that would work.

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00:05:07.820 --> 00:05:26.579
Bas Overtoom: And then, yeah, stay tuned, because as you know, we always have a very special, yeah, offer, to offer some of the webinar, participants, to do a first, let's say, yeah, pilot project with us on that, and we will talk a bit more about it. So, stay tuned.

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00:05:27.560 --> 00:05:39.589
Bas Overtoom: Then to the next slide. Before we dive into the nitty-gritty of the regulations and all those interactions and the requirements, yeah, we were just keen to understand from the audience

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00:05:40.100 --> 00:05:53.240
Bas Overtoom: how familiar are you, actually, with the general product safety regulations? Because we see that, we speak to some clients, and people are, like, not familiar at all with it, while it's an important regulation. So I think the…

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00:05:53.510 --> 00:05:56.049
Bas Overtoom: Question is coming up.

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00:05:59.790 --> 00:06:01.190
Bas Overtoom: the Q&A.

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00:06:03.970 --> 00:06:08.349
Bas Overtoom: Yeah, there it's coming, and… I would just ask you to…

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00:06:08.890 --> 00:06:20.059
Bas Overtoom: look at it, the question is, it's a scale, I'm not familiar at all, that's why I'm here, or I've heard about it, but I'm not really sure. I'm learning. I understand, but…

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00:06:20.160 --> 00:06:32.659
Bas Overtoom: kind of what we need to do, what we really need to get going, or yeah, we are busy getting going, or hey, actually, we have already kind of probably done it all, I'm just here to get validated that that's truly the case, that's also important.

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00:06:32.660 --> 00:06:40.269
Bas Overtoom: So please take your answer, take your time to click it away, and with the Q&A in the end, we will, yeah.

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00:06:40.370 --> 00:06:57.959
Bas Overtoom: come back to it. So, basically, also, the setup of this webinar is that we will spend another 25 minutes on bringing you all the content that I just introduced, and that we'll have a little bit of time to talk and pick up some questions and reflect a bit also on these poll results.

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Bas Overtoom: together. So that, as an introduction, and now leaving it over to Monica to kind of bring us through this regulation and talk on the nitty-gritty.

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00:07:08.710 --> 00:07:10.870
Bas Overtoom: And, Monica, over to you.

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00:07:11.850 --> 00:07:29.779
Mónica Fernández Peñalver: Perfect, thank you, Baz. So I will be speaking about the actual content of the GPSR, what it means, and what does it mean in practice. The main thing we need to understand about this regulation is that it's a catch-all regulation, and we will speak

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Mónica Fernández Peñalver: more about that. Its aim is to ensure that there's uniformity on rules and standards on product safety when it comes to consumer products all across the EU.

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Mónica Fernández Peñalver: So, if we were to summarize a regulation in a page, this is what it would look like. It's important to understand that it affects consumer products only, so it's good to have the definition of consumer product handy, and here is a simplified version of the definition that we find in the regulation itself.

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Mónica Fernández Peñalver: It is any item, it could be physical, digital, or a connected item.

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Mónica Fernández Peñalver: That is used, or likely to be used by consumers.

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Mónica Fernández Peñalver: whether they pay for it or not, could also be renting or other methods, including items used as part of a service. So, that covers quite a wide range of products when we talk about consumer products under the definition of the GPSR.

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Mónica Fernández Peñalver: And what we need to understand is that it impacts all products, whether they're already being regulated or not, by… whether they're already CE marked or not. The GPSR applies anyways. It is, like, this really big,

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Mónica Fernández Peñalver: Net that will cover, almost all, if not all, consumer products.

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Mónica Fernández Peñalver: so not only did the scope expand, but so did the definition of safety, so it is important to understand that what the GPSR brings, new in comparison to the General Product Safety Directive.

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Mónica Fernández Peñalver: Is that the… the… it now includes physical, mental health, and social well-being,

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00:09:25.460 --> 00:09:45.329
Mónica Fernández Peñalver: And expanded to cover also Internet of Things and artificial intelligence within the scope of the regulation. We will talk more about what the actual obligations are in the next few slides, but we can already see that they even explicitly mentioned the assessment

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Mónica Fernández Peñalver: of AI-related functionality, which is something that we're gonna touch on today, because, as we all know, in today's world, we have a lot of

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Mónica Fernández Peñalver: AI features embedded in our smart TVs, in our phones, in our vacuum cleaners, so, it is not uncommon

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00:10:06.450 --> 00:10:16.080
Mónica Fernández Peñalver: to now, as a manufacturer, if you're a manufacturer of these consumer products, to have to, specifically assess the AI functionality of these.

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Bas Overtoom: Yeah, and…

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00:10:17.810 --> 00:10:18.369
Mónica Fernández Peñalver: Good morning!

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Bas Overtoom: Emphasize that, so, the GPSR is a very wide regulation, but today is really what Monica mentioned.

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00:10:28.120 --> 00:10:44.030
Bas Overtoom: the focus on the AI safety assessment requirements for today. So, looking at that, please understand it has a wider implication for your product, but specifically on those, we will bring the focus.

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00:10:44.590 --> 00:10:45.240
Mónica Fernández Peñalver: Yeah.

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Mónica Fernández Peñalver: Exactly. So, but before we move forward, maybe we can have a quick recap and understand what is the difference between the GPS… the General Product Safety Directive and the General Product Safety Regulation. The reason they… they, built this regulation is because previously the directive allowed each EU country to implement

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Mónica Fernández Peñalver: The rules differently, which led to different… to quite a variety in terms of enforcement methods.

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Mónica Fernández Peñalver: And furthermore, the directive only covered consumer products that were not already regulated by sector-specific laws.

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Mónica Fernández Peñalver: So we can see that in comparison to the General Product Safety Directive, the GPSR is way stronger in the sense that it applies directly and uniformly across EU member states.

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Mónica Fernández Peñalver: And it, broadens the scope to cover all consumer products, whether they are already regulated by sector-specific laws or not.

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00:11:51.440 --> 00:12:15.480
Mónica Fernández Peñalver: So, what is new in the GPSR, aside of what I just mentioned? We mentioned it a little bit already in the one-pager, but just to emphasize again, the regulation expands consumer product safety law to cover digital, connected, and AI-enabled products, so these are explicitly mentioned in the regulation.

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Mónica Fernández Peñalver: It's not just interpretation. And it expands the definition of safety, so we don't… we also need to think about safety and

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00:12:25.000 --> 00:12:40.630
Mónica Fernández Peñalver: Risk assessments in… in accordance to… to not only physical and mental health risks, but also social well-being, in general with… when one is using, making use of these consumer products.

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00:12:40.640 --> 00:12:47.370
Mónica Fernández Peñalver: The main thing is that it introduces the need to do a continuous risk assessment.

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Mónica Fernández Peñalver: Ensuring that you cover these new, safety rules, and implement a post-market monitoring so that the risks are identified and monitored all throughout the product's lifetime.

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00:13:02.400 --> 00:13:04.899
Mónica Fernández Peñalver: And when it comes to…

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Mónica Fernández Peñalver: to monitoring those risks, it also includes implementing cybersecurity measures and taking into account any cybersecurity risks that could occur, with the use or the deployment of the products.

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00:13:21.690 --> 00:13:37.140
Mónica Fernández Peñalver: When it comes to the obligations, there are very specific things, such as technical documentation that has to be kept for at least 10 years of not just the full product, but even the digital elements of the product.

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00:13:37.180 --> 00:13:56.829
Mónica Fernández Peñalver: Risk assessment, we already, we already went through, but we need to cover physical, mental, AI, and cybersecurity risks. Then lifecycle monitoring, is part of, appropriate, risk management, in order to, to do it, if,

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00:13:56.910 --> 00:14:02.820
Mónica Fernández Peñalver: Efficiently and, and, robustnessly.

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Mónica Fernández Peñalver: And then, when it comes to cybersecurity and AI, secure data, ensuring that the data that these digital elements are handling is secure, make sure that we can block any potential attacks, and implement oversight measures where viable.

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00:14:21.260 --> 00:14:35.190
Mónica Fernández Peñalver: And, other… the other obligations are more on if there are any, of course, any updates to the product, we need to reassess is… reassess it, considering these updates.

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00:14:35.980 --> 00:14:49.579
Mónica Fernández Peñalver: And then, it also sets out rules on how to, process any complaints, recalls, or any, incident, reporting, measures.

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00:14:51.180 --> 00:15:13.909
Mónica Fernández Peñalver: When it comes to the timeline, well, we are going to share these slides, so you will always have these slides handy, but when it comes to the timeline, the main thing to understand is that this regulation is already enforced. This is what Baz already said in the introduction. It's been enforced since 2024, and in fact, since 2025, there is market surveillance.

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Mónica Fernández Peñalver: So, even though we are in the middle of certain regulatory developments that are catching a bit more attention from people, like the EU AI Act or any potential delays around it, this regulation is already a reality, and

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Mónica Fernández Peñalver: Our clients are starting to… to realize that this is something that they need to pay attention to.

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00:15:39.530 --> 00:15:55.320
Mónica Fernández Peñalver: And then, by 2034, since it's 10 years since the enforcement of the regulation, that's when the 10-year technical documentation cycle reaches maturity, and the documentation doesn't have to be kept anymore.

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00:15:56.970 --> 00:16:17.809
Mónica Fernández Peñalver: So, if we go through an example of a use case, what people would have to do on the GPSR, we can pretend they are… there's this product already in the market, and their parents are buying a smart baby monitor. The smart baby monitor, obviously has digital elements embedded.

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Mónica Fernández Peñalver: And And they bought it from an online shop.

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Mónica Fernández Peñalver: Then, after the product has been deployed in the market, it is identified that there is actually a security flaw in the product, so hackers can potentially access the video feed.

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Mónica Fernández Peñalver: because the device can allow some weak default passwords to be entered.

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Mónica Fernández Peñalver: So, technically, when this would happen, under the GPSR, this would mean that the manufacturer must treat this as a digital safety risk, and inform consumers of this, as well as authorities, as soon as possible, and of course, provide a remedy against it.

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00:17:04.329 --> 00:17:16.170
Mónica Fernández Peñalver: So this could be a mandatory update of, that, that fixes such a security issue, or, or, putting it away from the market.

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Mónica Fernández Peñalver: Then with regards to that last point, then online marketplace must also cooperate and remove these unsafe versions of the product from the market.

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00:17:28.079 --> 00:17:47.830
Mónica Fernández Peñalver: And then, last but not least, parents should get a clear alert explaining the risk and the steps that they need to… to do to make sure, that… to either return the device or make sure that their device comes back to… to the acceptable safety standards.

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00:17:51.140 --> 00:18:15.379
Mónica Fernández Peñalver: So, we already mentioned that the GPSR serves as a catch-all regulation, but what does this mean? We already said that it covers, or the products that fall in scope doesn't matter whether they are already regulated by sector regulation, sectoral directives or regulations, so it doesn't matter if the product is CE marked or not.

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00:18:15.380 --> 00:18:28.869
Mónica Fernández Peñalver: not, the GPSR still applies. Of course, for a product that is not CE marked and is not regulated by sectoral regulations, the GPSR would be the main and only product safety law that applies.

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00:18:28.870 --> 00:18:40.900
Mónica Fernández Peñalver: If the product is already regulated by sectoral regulations, then the GPSR applies to the risks that have not been covered by

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00:18:40.930 --> 00:18:47.460
Mónica Fernández Peñalver: The sectoral regulations, so it applies onto the gaps that, we find.

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Mónica Fernández Peñalver: So, the idea is just to catch all the risks that could be falling through any regulatory gaps that we find today to ensure that all physical and digital risks are covered.

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00:19:06.540 --> 00:19:21.170
Bas Overtoom: Maybe just to emphasize this point, and I think we'll come back a little bit to it when it comes to the AI Act also, to give it a bit more detail, but we see that there's always the focus on specific product regulations that you have, or now the AI regulations.

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Bas Overtoom: But the GPSR regulations are always there. It could be, in some cases, that

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Bas Overtoom: Yeah, there's nothing additional. For example, if you have a high-risk AI system according to EU AI Act, and all the steps that are required there, you're also gonna do almost… you're gonna do, actually, the GPSR requirements already, so sometimes there is not anything additional coming from the GPSR.

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00:19:44.420 --> 00:20:00.459

Bas Overtoom: But it can be that you're following your product regulation, and you're still missing out, some additional requirements for GPSR, or what Monica mentions here. Maybe you think you have no requirements, but still from a GPSR. So I think having this as the minimum baseline.

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00:20:00.460 --> 00:20:16.459
Bas Overtoom: is there. So this is the absolute minimum that you have to do if you want to bring out your product in the EU market, and yeah, let's say, conform with compliance, you have your CE mark, Doshier will dive into that in a bit, detail maybe later also.

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Bas Overtoom: This is kind of the minimum baseline that is required, and you need to be able to show this documentation at all times if an authority asks for it.

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Mónica Fernández Peñalver: Yep.

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00:20:27.430 --> 00:20:42.500
Mónica Fernández Peñalver: And, how Baz explained earlier in the introduction, we see, this being applied quite well when it comes to AI-enabled products, so in terms of this catch-all behavior.

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00:20:42.500 --> 00:20:50.909
Mónica Fernández Peñalver: of this regulation, we know that even if your AI-enabled product is considered low risk under the EU AI Act.

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Mónica Fernández Peñalver: the GPSR would still apply, and you would still have to do risk assessments, on the AI functionalities of your product.

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00:21:01.490 --> 00:21:09.700
Mónica Fernández Peñalver: So, given that we are talking a little bit about AI and the AI Act, it would be good to have a bit of a recap

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Mónica Fernández Peñalver: for those who… who need it, the AI Act in very… in a very summarized way. It uses this risk-based approach, where it categorizes AI systems

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Mónica Fernández Peñalver: Based on its risk, to… to define them as high risk, limited risk, or low risk.

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Mónica Fernández Peñalver: And then as separate categories, we have prohibited AI practices, which are considered… they are completely prohibited to be placed and used in the EU market.

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00:21:40.290 --> 00:21:53.490
Mónica Fernández Peñalver: And then general purpose AI is treated separately because of the unique nature of these models and how they need to be handled and assessed.

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00:21:53.810 --> 00:22:08.040
Mónica Fernández Peñalver: So, as we can see in this table over here, we can see that most of the obligations and the strict obligations mostly apply to the high-risk AI.

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00:22:08.120 --> 00:22:23.050
Mónica Fernández Peñalver: And, no obligations at all apply, or very minimal, practices apply to the low-risk AI. So they're normally only just subject to codes of conduct.

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00:22:24.140 --> 00:22:35.050
Mónica Fernández Peñalver: Now, with regards to the AI Act, we cannot ignore that there has been some proposals to delay some of the implementation of these obligations.

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Mónica Fernández Peñalver: So, initially, the obligations for high-risk AI, they are coming on the 2nd of August of 2026.

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Mónica Fernández Peñalver: And the remaining obligations, apply in August 2027.

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Mónica Fernández Peñalver: Now, however, the… very recently, a couple weeks ago, the digital omnibus package was released, where it proposes to delay some of these obligations because of the lack of

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Mónica Fernández Peñalver: harmonized standards. Since these harmonized standards that are being developed in order to support the implementation and the conformity assessments of the AI Act.

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Mónica Fernández Peñalver: these are being delayed, so that, hence why they are proposing the delay of the obligations. What this means is that, about a period of between 6 to 12 months that these obligations could be delayed.

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00:23:32.790 --> 00:23:52.559
Mónica Fernández Peñalver: But the main thing to understand about all of this is that we are talking about a proposal. So, at the end of the day, at this current time, these proposed delays have not been accepted, and even if they are accepted, the Commission might not accept

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00:23:52.560 --> 00:24:11.969
Mónica Fernández Peñalver: the time frame that is being proposed. So they might say, okay, we can delay these obligations, but not for an entire year, maybe only for a couple of months. So, we wanted to give you a briefing about this, because it's important to know what's going on and to understand it.

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Mónica Fernández Peñalver: But our main advice is to continue working towards the AI Act, as normal.

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Mónica Fernández Peñalver: Because we don't know, if these, if these delays will be accepted or not.

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Mónica Fernández Peñalver: But having that in mind, let's say you are a manufacturer or provider of an AI-enabled product, and you look at the AI Act categories, and you look at the timeline, and you think, well.

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Mónica Fernández Peñalver: Mine does not fall anywhere on this time… nowhere in this timeline, and I'm… I'm for sure a low-risk AI, provider.

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Mónica Fernández Peñalver: So, I have nothing to do with these obligations, but that is the wrong mentality, that is false. You have to apply the GPSR no matter what, because the GPSR still applies to low-risk AI. In fact, it applies to all of them. So, even if you're limited-risk AI, if there is any gaps that the EU AI Act does not

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00:25:13.500 --> 00:25:21.140
Mónica Fernández Peñalver: fulfill to assess, but it is being assessed by the GPSR, you have to… to assess them.

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Mónica Fernández Peñalver: So let's not forget that the GPSR is a catch-all regulation, and more likely than not, your products fall under it.

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00:25:31.770 --> 00:25:40.510
Mónica Fernández Peñalver: I'll give it over, back to you, Baz, as I think you can give us a good briefing of what this means in practice.

123

00:25:41.620 --> 00:25:46.279
Bas Overtoom: So basically, when it comes to the requirements of the GPS,

124
00:25:46.310 --> 00:26:05.339
Bas Overtoom: DPRS. This is… Monica already outlined it in a few nice words, I think, but here, more simplified. What it requires is a couple of things. It requires that you have the technical documentation on your product, but also on the AI and digital components that are in there, so just products.

125
00:26:05.360 --> 00:26:16.920
Bas Overtoom: Yeah, hardware specifications is not sufficient. You need to have technical documentation. Maybe you already have it, then it's fine, but just make sure that you have it ready.

126
00:26:17.020 --> 00:26:23.940
Bas Overtoom: That's one. Then you need to inform your users, consumers, on…

127
00:26:24.450 --> 00:26:27.869
Bas Overtoom: the fact that there's an AI in the product.

128
00:26:28.430 --> 00:26:35.019
Bas Overtoom: And how it works, and what they can expect. And it can be in a user manual, it can be online, there's different ways to do it, but…

129
00:26:35.020 --> 00:26:48.699
Bas Overtoom: It is a key requirement that your users should be aware and informed about the fact that an AI is participating in the decision-making process of the product, or in the optimized use of the product, of all these kind of things.

130
00:26:48.900 --> 00:26:56.930
Bas Overtoom: And then there is some sort of quality monitoring, and I think it's good to mention here that this doesn't mean that it will be an…

131
00:26:57.820 --> 00:27:10.540
Bas Overtoom: full-on, continuous monitoring of all decision-making, or all logging of all AI things, but there needs to be some kind of quality monitoring and feedback look in place that you can show with dry eyes.

132
00:27:10.540 --> 00:27:18.040
Bas Overtoom: that you have a good view on the fact that the AI stays functioning well over time,

133
00:27:18.040 --> 00:27:22.459
Bas Overtoom: So, proving that you have something in place for that is the third thing.

134
00:27:22.710 --> 00:27:32.440
Bas Overtoom: These things might seem good standard safety requirements for any product, hence you might be already doing it, so…

135
00:27:32.540 --> 00:27:45.060
Bas Overtoom: that's already many of the requirements taking on. And then, there is the last thing that we want to focus also a bit of attention on, and that's the general risk assessment for AI and digital components.

136
00:27:45.060 --> 00:27:55.520
Bas Overtoom: Because by the safety regulation, it stated that you need to do an, general, safety, of a general assessment on the risks.

137
00:27:56.060 --> 00:27:56.750
Bas Overtoom: and…

138
00:27:57.200 --> 00:28:16.660
Bas Overtoom: So you need to be able to show that you have done this assessment, and then also, there might come out specific risks, we don't know. It might come out of the assessment

that you say, yeah, there's very limited risk, because it was already a low AI system, and I did a good risk assessment, a professional risk assessment, and it was confirmed there's limited risk.

139
00:28:16.660 --> 00:28:24.249
Bas Overtoom: then you need to do nothing additionally except the three things that I already mentioned, the three other requirements, which is kind of basic hygiene.

140
00:28:24.250 --> 00:28:30.249
Bas Overtoom: But, if… Specific risks come out of the risk assessment, safety risk or other risks.

141
00:28:30.250 --> 00:28:47.779
Bas Overtoom: Then you are also automatically obliged to show that you are taking mitigating actions, and that's the total thing on the right hand, that's undefined, that is the result of your own risk assessment, but you need to be also able to show that you are taking the mitigating actions

142
00:28:47.780 --> 00:28:52.599
Bas Overtoom: towards this, thing. And basically,

143
00:28:53.800 --> 00:29:13.179
Bas Overtoom: that is basically all you need to do, and if you make this, yeah, as part of your file, for your self-declaration on CE marking, for example, then you are good to go. And this is basically the process and the requirements to explain it in very simple terms.

144
00:29:13.180 --> 00:29:16.309
Bas Overtoom: So what does this all mean? Maybe the next slide.

145
00:29:16.600 --> 00:29:23.910
Bas Overtoom: Yeah, I think, just to summarize again, I think something that Monica already explained a little bit is that

146

00:29:24.860 --> 00:29:41.389
Bas Overtoom: there's… when you look at the comparison, again, with the EUAI Act and the GPSR, is that prohibited AI, yeah, of course, that is not allowed to bring to the market. The GPSR doesn't say anything about it. The GPSR, again, it is not a risk-based approach.

147
00:29:41.390 --> 00:29:46.120
Bas Overtoom: So, it contains for all AI or digital elements, it's the same thing.

148
00:29:46.190 --> 00:29:54.790
Bas Overtoom: Then, for low AI risk, it is the requirements that I just outlined, because from the EUAI Act, you don't have any requirements.

149
00:29:54.810 --> 00:30:13.750
Bas Overtoom: For limited risk, you have the GPSR requirements plus the standard transparency requirements that the EUAI Act says, which is partly overlapping with technical documentation and user information, but I think the EUAI Act is a little bit more elaborated on it.

150
00:30:13.810 --> 00:30:23.069
Bas Overtoom: And then you have the high risk that must go and have a conformity assessment, according to the AI, and do still also a risk assessment.

151
00:30:23.400 --> 00:30:29.470
Bas Overtoom: Mitigate any potential additional risks that are not a catch-all in the high-risk system.

152
00:30:29.480 --> 00:30:46.050
Bas Overtoom: It might be that if you go to the whole AI, especially there, you go to this AI conformity assessment, yeah, that you find that the GPSR requirements are already completely integrated in the things you have done, so there's not much additional, but yeah, just do the double check.

153
00:30:46.060 --> 00:30:49.100
Bas Overtoom: I would say. So this is basically,

154
00:30:49.590 --> 00:30:53.199
Bas Overtoom: kind of the understanding. Yeah, maybe…

155
00:30:53.970 --> 00:31:13.320
Bas Overtoom: there it goes. This is what you have to do. If you have a consumer product that you are bringing to Europe, manufacturing Europe, or you're manufacturing it outside and you want to bring it to the European market, you need to get these four things in place to be able to carry your CE mark, if you have an AI-enabled product, yeah?

156
00:31:13.330 --> 00:31:18.700
Bas Overtoom: So, if you have that, please be aware and start to do it.

157
00:31:19.080 --> 00:31:28.670
Bas Overtoom: We can help you, of course, with that. This is our bread and butter, and what we promised is a nice, let's say.

158
00:31:28.910 --> 00:31:41.630
Bas Overtoom: Yeah. Present, for, you here in the webinar, our listeners, is that we would like to invite two companies to, to go through, with us through an,

159
00:31:41.670 --> 00:31:50.250
Bas Overtoom: and high-level risk assessment, so the left part, here, and, we offer that for free. So.

160
00:31:50.320 --> 00:32:02.409
Bas Overtoom: no cost involved for two companies that say, we want to get going with the compliance for GPSR, and so it's not the whole complete package, but we will do the risk assessment

161
00:32:02.410 --> 00:32:18.440

Bas Overtoom: with you for free to identify any specific risks, and that will give you kind of a very good overview if there's any specific things that you need to do, apart from the three other things that are mentioned here to be fully GPSR compliant on your AI elements.

162
00:32:19.620 --> 00:32:27.250
Bas Overtoom: Next slide. So, if you are, I think this I already explained. So, the next slide,

163
00:32:27.290 --> 00:32:35.589
Bas Overtoom: To kind of maybe elaborate a little bit more about what we will mean and what we are doing with such a risk assessment.

164
00:32:35.590 --> 00:32:45.609
Bas Overtoom: Of course, as Namput Digital, we're quite experienced in this. We are making use of a couple of risk frameworks. Predominantly, we are using IBM's

165
00:32:45.610 --> 00:32:57.069
Bas Overtoom: Yeah, AI Risk Atlas as the basis to go through it. It's a quite elaborate risk atlas that we are using in many engagements. We think it's particularly good.

166
00:32:57.070 --> 00:33:15.709
Bas Overtoom: It tests us out over 904 risks, also optimized for generative and agentic AI, so not only, yeah, let's say the traditional AI, but quite forward-looking, and here you see some of the key categories that will be, looked at

167
00:33:15.710 --> 00:33:27.360
Bas Overtoom: while you go through the assessment. So, if you're interested to be one of those two companies, we give two prizes away. Everybody else, of course, we can just do it as an engagement with you.

168
00:33:27.600 --> 00:33:37.629
Bas Overtoom: But we will go with you through these risks of the IRM risk at last, and together define, okay, what risk are there in, then, in scope for my product?

169
00:33:37.780 --> 00:33:44.890
Bas Overtoom: N, and… outline if there's any additional mitigating actions that you need to, to take. So…

170
00:33:45.500 --> 00:33:54.769
Bas Overtoom: If you're interested in this offer and want to get going, this is the moment to catch your phone and apply.

171
00:33:54.820 --> 00:34:06.989
Bas Overtoom: and scan. And with that, I think we will dive into… we give you a moment to, to quickly make the picture. As Monica said, we will go into, some of the,

172
00:34:08.659 --> 00:34:20.900
Bas Overtoom: discussions, Q&A right now. We have a few questions already come up, and please make your interest, and then we will go into the questions. Before that, I wanted to give you the results of the poll.

173
00:34:20.900 --> 00:34:30.119
Bas Overtoom: And I think what I see here, I think there was, yeah, less than 5% of the people, say they have been finished with the,

174
00:34:30.540 --> 00:34:32.900
Bas Overtoom: GPSR,

175
00:34:33.350 --> 00:34:50.929
Bas Overtoom: almost 20%, so in total, a quarter say, hey, we are quite familiar, we're actually preparing for compliance, and then, there is, yeah, 3 quarters that are, busy getting ready. With most of them, they are…

176
00:34:51.199 --> 00:35:10.749
Bas Overtoom: yeah, either busy preparing, and I need to know… I know what I need to do, and a few of them, they're like, yeah, I'm just here to find out what I need to do, and there were a few

of you here, about 10% that says, yeah, I was not aware of the GPS hours at all. So these are things, like, that 3 quarters of the people still need to work on it.

177
00:35:10.800 --> 00:35:17.580
Bas Overtoom: And I hope that some of you are going for this risk assessment.

178
00:35:17.580 --> 00:35:34.260
Bas Overtoom: In the meantime, Monica showed you also our LinkedIn group. I think that's quite interesting, where we are posting on these things, like the GPSR and all other key regulations that you need to know about, and also some of the forward-looking topics as,

179
00:35:35.310 --> 00:35:46.529
Bas Overtoom: As this one, a forward-looking topic, sorry, as agentic AI, generative AI, etc. So…

180
00:35:46.530 --> 00:36:04.439
Mónica Fernández Peñalver: And, maybe to elaborate on that, we're also, posting and keeping track of, like, you know, we already talked about the potential delays to the AI Act, or any other regulatory changes, or, yeah, like, developments around

181
00:36:04.440 --> 00:36:18.180
Mónica Fernández Peñalver: any regulation that touches, not just on AI, but digital products, or physical products with digital elements in it. So, very… given our Nemco DNA, we're very, very,

182
00:36:18.470 --> 00:36:42.280
Mónica Fernández Peñalver: deep into product legislation, and also monitoring how these product legislations are adapting to the new technological developments. So, we are seeing that some regulations are faster than others. So, as we know, for example, the medical device regulation has adapted to

183
00:36:42.280 --> 00:36:44.190
Mónica Fernández Peñalver: To ensure that it covers.

184
00:36:44.190 --> 00:36:59.630
Mónica Fernández Peñalver: AI embedded in medical devices, and then people in the sector will know that they have to not only keep track and take into account any changes to the MDR, but also apply the EU AI Act

185
00:36:59.630 --> 00:37:17.270
Mónica Fernández Peñalver: And so on. We see things like that happening all the time, and then there are regulations that are a bit slower when it comes to catching up to the technological developments. You can keep track of all these things through our LinkedIn page, and of course, if you ever have

186
00:37:17.270 --> 00:37:39.160
Mónica Fernández Peñalver: any specific questions, you can always reach out to me or Baz. Maybe talking about questions, I think I've received a couple times questions about the risk assessments. Obviously, like Baz has already said, many, many companies are already doing their risk assessments, maybe because of… of…

187
00:37:39.230 --> 00:37:46.519
Mónica Fernández Peñalver: Having to comply with the radio equipment directive, or any other directives or regulations.

188
00:37:46.520 --> 00:38:06.339
Mónica Fernández Peñalver: So the main question is, do I need to do a completely separate risk assessment in order to cover these new obligations? And the main answer is no, you can expand the current risk assessments, it's just about knowing how to expand it and making sure that the gaps are still filled.

189
00:38:06.340 --> 00:38:10.690
Mónica Fernández Peñalver: So, if you are one of these companies that are winning,

190
00:38:11.000 --> 00:38:19.769
Mónica Fernández Peñalver: our offer on the risk assessments, we can take that into account, when it comes to… to…

191
00:38:19.810 --> 00:38:36.280
Mónica Fernández Peñalver: to assessing your AI risks, and how can you incorporate these, identified risks and mitigation measures into your current existing, risk management policies, and so on.

192
00:38:36.690 --> 00:38:38.150
Mónica Fernández Peñalver: So…

193
00:38:38.150 --> 00:38:42.480
Bas Overtoom: A few questions coming in, Monica. I mean, you can get the slides away, I think people can then also…

194
00:38:42.480 --> 00:38:42.830
Mónica Fernández Peñalver: Okay.

195
00:38:42.830 --> 00:38:51.080
Bas Overtoom: our, see our faces when we are a little bit going into the Q&A. So, one person is also asking, we are talking about risk assessment.

196
00:38:51.080 --> 00:39:01.569
Bas Overtoom: and risk level, so, I think it is also good to… so, is a risk level determined for the AI device? And maybe you can elaborate a little bit

197
00:39:01.570 --> 00:39:11.150
Bas Overtoom: about, yeah, the difference between risk categorization on the one hand and a risk assessment, because I can understand that might be a little bit confusing. Monica, can you share a little bit?

198
00:39:11.990 --> 00:39:24.269
Mónica Fernández Peñalver: Yes. So, when it comes to risk categorization, we often talk about it from the lens of the EU AI Act.

199
00:39:24.270 --> 00:39:37.530
Mónica Fernández Peñalver: Simply because it's the most mature regulation that we have around AI globally, and it uses this approach, and it has very clear criteria on what

200
00:39:37.590 --> 00:39:45.500
Mónica Fernández Peñalver: Risk categories belongs to, to which, oh, which products belong to which risk categories.

201
00:39:45.570 --> 00:40:09.050
Mónica Fernández Peñalver: It really depends, so there's things to consider, like, whether the AI is used as a safety component of a regulated product, that would be immediately considered a high-risk AI. Whether the AI enables biometric identification features, or so on, that would also be considered a high-risk AI.

202
00:40:09.050 --> 00:40:11.680
Mónica Fernández Peñalver: And then there are other use cases that we've

203
00:40:11.680 --> 00:40:16.540
Mónica Fernández Peñalver: encountered where there is a bit more of a… of,

204
00:40:16.540 --> 00:40:37.980
Mónica Fernández Peñalver: gray and unclear zone, and it requires a bit more, interpretation of the Act and more diving deeper into the recitals to see what the regulators are really meaning when it comes to the criteria. And this is something that, we are quite,

205
00:40:38.060 --> 00:40:51.869
Mónica Fernández Peñalver: experienced with at this point, based on all the risk categorizations that we had. So that is risk categorization, that is, this process does not identify the risks that the AI in itself

206
00:40:51.980 --> 00:41:11.960

Mónica Fernández Peñalver: has, or could, could lead to, and does not, therefore, within the process, let you know of which measures you need to implement in order to mitigate these risks. This is done through the risk assessment, and then this will lead to the

207
00:41:11.960 --> 00:41:30.349
Mónica Fernández Peñalver: To, identifying what are the best measures, whether they are technical measures, or whether there are organizational measures, or deployment measures, whether it's a human that has to, through certain human oversight measures.

208
00:41:30.350 --> 00:41:39.449
Mónica Fernández Peñalver: prevent or minimize these risks, or if it is something that can be embedded into the design. These kind of…

209
00:41:39.590 --> 00:41:50.760
Mónica Fernández Peñalver: things are only identified through risk assessments. So this is the stuff that we would identify, in the risk assessment that we're offering in the webinar today.

210
00:41:50.990 --> 00:41:56.039
Bas Overtoom: Yeah, thank you, and maybe just to summarize it again, a lot of words, but well spoken.

211
00:41:56.040 --> 00:42:14.590
Bas Overtoom: So the risk assessment is defining the risks. That is what we offer, a risk categorization, so the risk level that is, for example, according to something, like an EOA Act. That's the risk categorization. That was the offer in the last webinar for the people that remember it. That's also a service, of course, we can give out anytime.

212
00:42:14.590 --> 00:42:23.650
Bas Overtoom: But, they are two different things, and it might make it a bit, confusing. Additionally, here, I, I have another,

213
00:42:25.120 --> 00:42:30.780
Bas Overtoom: Interesting, interesting, question.

214
00:42:31.030 --> 00:42:40.059
Bas Overtoom: So, is there any requirement for a human in the loop from a GPSR perspective, Monica?

215
00:42:42.290 --> 00:42:55.399
Mónica Fernández Peñalver: So the GPSR doesn't define… so a human in the loop, would be a risk mitigation measure, but, the GPSR does not draft

216
00:42:55.470 --> 00:43:16.240
Mónica Fernández Peñalver: what measures one should implement, as can… it's a regulation that is so broad that it aims to cover products across different sectors that it cannot afford to be specific about those things. So, no, it's not a requirement, but of course, if your risk assessment

217
00:43:17.900 --> 00:43:31.220
Mónica Fernández Peñalver: says that, or leads to the identification of a risk that… that needs human oversight, then you would have to apply it, in order to mitigate the risks under the GPSR.

218
00:43:31.220 --> 00:43:44.560
Bas Overtoom: That's well spoken. Thank you, and maybe a last question, and then we need to round off other questions we can answer you by email, and I think this one is particularly, important for,

219
00:43:44.730 --> 00:43:54.530
Bas Overtoom: For all to know, what are actually the penalties for in compliance with this, general product safety regulation, is the question.

220
00:43:55.770 --> 00:44:09.569
Mónica Fernández Peñalver: If I remember correctly, I think it's up to 4% of global annual turnover. That can be the penalty, for noncompliance.

221
00:44:09.570 --> 00:44:19.739

Mónica Fernández Peñalver: But, I would have to double-check that. I'm not sure if we had it in the slide, but there is for sure, a financial penalty to

222
00:44:19.740 --> 00:44:23.869
Mónica Fernández Peñalver: To consider, and… and that will be it.

223
00:44:24.930 --> 00:44:32.019
Bas Overtoom: And maybe additionally, there is this, X percent of global turnover, which is all there always, of course.

224
00:44:32.070 --> 00:44:45.550
Bas Overtoom: yeah, quite a significant amount, but very importantly, that you have to bring your product off market, yeah? So I think sometimes you can maybe define will be… financial fine will be always.

225
00:44:45.550 --> 00:44:54.179
Bas Overtoom: Yeah, that's the maximum fine, huh? This, this, this 4% of your, or two and a half, I think it was, or 4%.

226
00:44:54.180 --> 00:44:56.659
Mónica Fernández Peñalver: Oh, it's 4%, it is in the slides, yeah.

227
00:44:56.660 --> 00:45:03.189
Bas Overtoom: 4% of your turnover, but the key thing is that the product needs to be going off the market, you need to re-emphasize all.

228
00:45:03.190 --> 00:45:05.590
Mónica Fernández Peñalver: Yeah, yeah, it doesn't… yeah.

229
00:45:05.590 --> 00:45:21.219
Bas Overtoom: Gigantic for something that is a very small, let's say, project to initiate. So, we all advise you, to, to get going. It's still possible until, Monday to register for your,

230
00:45:21.320 --> 00:45:31.429
Bas Overtoom: free assessment, so if you are interested to get going for free, please register. Monday, end of day, we will announce the winners.

231
00:45:31.470 --> 00:45:51.390
Bas Overtoom: And, yeah, if there's this topic or any other topic that you think, yeah, maybe for me it's not so much GPSR, but it is the Data Act, or I just want to look into getting an AI management system in my organization, or I still have a question on this risk categorization for the EUAI Act.

232
00:45:51.390 --> 00:45:58.000
Bas Overtoom: that can all be also relevant, then you know where to go. We are here, the Global Expert Team.

233
00:45:58.000 --> 00:46:08.799
Bas Overtoom: on this topic, and we look forward to support you in this journey towards, on the one hand, trusted AI that you can bring into your products and you can bring to market with safety and confidence.

234
00:46:08.820 --> 00:46:19.379
Bas Overtoom: To help your clients, yeah, make the world a better place, so to say, or, enjoy convenience, or whatever the functionality is that you're, you're bringing.

235
00:46:19.380 --> 00:46:39.839
Bas Overtoom: Thank you, Monica, for all your insights, and thank you, audience, for your active participation, and we look forward to see you in 2026. This was the last webinar of this year, but in January, we'll pick up the pace with new, interesting topics. I think the next

236
00:46:39.860 --> 00:46:56.030
Bas Overtoom: webinar will be on ISO standards, so the 42001, but also some very interesting ones on data that are very keen to know, so we'll keep bringing you, let's say, yeah, the latest and the greatest knowledge and insights on

237
00:46:56.030 --> 00:47:01.170
Bas Overtoom: On compliance and quality management for the digital worlds in which we are living.

238
00:47:01.210 --> 00:47:02.279
Bas Overtoom: Thank you all.

239
00:47:02.630 --> 00:47:04.830
Mónica Fernández Peñalver: Thank you. Thank you, everybody.