

Legal requirements for cloud solutions

With Prof. Dr. Marc Strittmatter, Prof. Dr. Christian Johner

Transcript

00:00:05 Speaker 1

Medical Device Insights.

00:00:08 Speaker 1

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

00:00:18 Speaker 1

We are experiencing waves of technology trends here.

00:00:21 Speaker 1

AI is currently hyped, but the topic of cloud has flattened out a bit.

00:00:26 Speaker 1

but often these are somewhat more flattened topics that are particularly relevant because they have become widely distributed.

00:00:33 Speaker 1

And of course, cloud is now relevant for medical device manufacturers from different angles.

00:00:39 Speaker 1

On the one hand, medical device manufacturers, companies that use cloud services, are also internal, but they are also those that use these services to be able to offer products.

00:00:51 Speaker 1

And this issue is not necessarily getting any easier legally

00:00:55 Speaker 1

And for this reason, I have called in an expert with whom we want to shed light in this podcast episode.

00:01:01 Speaker 1

What is all this legal framework around the topic of the cloud, which medical device manufacturers in particular should pay attention to, even when they make contracts or sign contracts?

00:01:13 Speaker 1

And I have invited Professor Mark Stritmatter, who introduces himself very briefly.

00:01:19 Speaker 2

Yes, good morning Christian, thank you for letting me be back in your beautiful studio and.

00:01:25 Speaker 2

I am very pleased that we can talk about cloud contracts today.

00:01:29 Speaker 2

It is therefore primarily a matter of a contract law view with all the trimmings from the customer's perspective, but also from the provider's perspective.

00:01:39 Speaker 2

We have a common past at H.T.W.G.

00:01:42 Speaker 2

in Constance.

00:01:43 Speaker 2

I saw I.T.

00:01:44 Speaker 2

and data protection law and continue to do so.

00:01:46 Speaker 2

Prior to that, I worked as a lawyer in the field of I.T.

00:01:51 Speaker 2

Right, and then I have a ten-year period at

00:01:54 Speaker 2

IBM Germany, where I was most recently head of the legal department.

00:02:00 Speaker 2

So IT law has almost always been my hobby and my subject matter, with which I am passionate, to which I am passionately connected.

00:02:10 Speaker 2

And today I advise companies on data protection projects, sometimes also on IT contracts of all kinds.

00:02:17 Speaker 2

But Cloud is my hobbyhorse in particular.

00:02:21 Speaker 1

What special are these

00:02:22 Speaker 1

Companies or the experience you have now gained with the companies that use such cloud applications, in which contexts do they usually use the cloud?

00:02:33 Speaker 2

So, the contexts are very broad.

00:02:35 Speaker 2

What I can see as a trend is that the core areas of the company processes, i.e. E.R.P., M.E.S., C.R.M., that they simply go fully into the cloud.

00:02:47 Speaker 2

This is also driven to a large extent by the fact that the

00:02:50 Speaker 2

large providers have turned their business models around and are actually forcing customers into the cloud.

00:02:56 Speaker 1

Yes, we also see that with the medical device manufacturers.

00:03:00 Speaker 1

So, if we just look at these two pages again, I had already teased it, on the one hand, as you just said, they use the cloud for their internal processes.

00:03:09 Speaker 1

About E.R.P.

00:03:10 Speaker 1

just reported, among the developing medical device manufacturers we naturally see many products from the Atlassian context.

00:03:19 Speaker 1

I think this is a good example of this, yes, all these on-premise solutions are gradually becoming unattractive or even switching them off completely at the medical device manufacturers, perhaps even specifically.

00:03:32 Speaker 1

We have a lot of customer feedback in the area, so not only development, but also customer feedback.

00:03:39 Speaker 1

I mention this because these are of course also regulatory processes and later also the operation.

00:03:45 Speaker 1

So, if you now perhaps think of a

00:03:46 Speaker 1

Tiger manufacturer thinks that the server parts usually run in the cloud.

00:03:52 Speaker 1

And I think that's a small difference that we now have with the medical device manufacturers compared to the other commercial enterprises that we also have.

00:04:02 Speaker 1

But the operation of central corporate processes, so to speak, that they migrate to the cloud, I think both have that in common.

00:04:11 Speaker 1

Yes, let's get straight into this legal topic, which

00:04:16 Speaker 1

Laws, which areas of law should a medical device manufacturer really have on its radar as an example in order to act in accordance with the law?

00:04:28 Speaker 2

Yes, OK, that's a big question with hopefully a crisp answer.

00:04:32 Speaker 2

Before I go into individual points, I would like to tie in with what you just said.

00:04:37 Speaker 2

This move to the cloud certainly has a lot of doubts and reluctance

00:04:43 Speaker 2

for many customers.

00:04:45 Speaker 2

What you can see is that the big providers simply don't really give customers a choice anymore about the, yes, the discounting, the pricing.

00:04:54 Speaker 2

They say, OK, you want a good price, here's the cloud price and here's the on-premise price.

00:05:00 Speaker 2

In some cases, cloud services are bundled in, which then run along virtually blindly, even though the customer wants to go fully on-premise.

00:05:08 Speaker 2

The topic of protection of secrets and data protection has been a major topic.

00:05:12 Speaker 2

It is

00:05:13 Speaker 2

and it still is.

00:05:15 Speaker 2

However, it has to be said that the big ones, not only the big ones, but also medium-sized ones, but those who may have a good hyperscaler behind them, simply have the issues well under control by now.

00:05:24 Speaker 2

I'm more of a fan of medium-sized companies because they are innovative, but sometimes size is also good when you have to act process-driven and very professionally, and there is a lot of progress in this area even among large companies.

00:05:38 Speaker 2

But to his legal question, perhaps

00:05:42 Speaker 2

First of all, a few points in advance, if you do cloud, you have to stay standard and go.

00:05:47 Speaker 2

This also means standard contracts, where there is sometimes no longer much room for manoeuvre.

00:05:52 Speaker 2

So you have to look at how standardized you make your own conditions or are the manufacturer's conditions.

00:06:00 Speaker 2

I always advise you to negotiate anyway, because sometimes the

00:06:06 Speaker 2

Negotiation of legal points, a leverage on commercial points.

00:06:09 Speaker 2

Yes, that's how things are often solved, if the provider absolutely wants to remain standard, then he just makes a commercial concession, then you have won something.

00:06:16 Speaker 1

So that I understand you correctly, you are now also talking about things like general contractual conditions in such a way that you should question them again and not accept them as non-contradictory and non-negotiable.

00:06:28 Speaker 2

Very good point, so first of all it's about the contract conditions as a whole.

00:06:32 Speaker 2

The central element is always the service descriptions,

00:06:35 Speaker 2

what do I get in the cloud at all, what is the availability known with the SLA service level agreements and then always general contract conditions behind them.

00:06:44 Speaker 2

At first glance, one would say, yes, we have to get involved now.

00:06:48 Speaker 2

I have to warn against this again, because in Germany there is the GTC law, which puts a kind of fairness filter over the contracts.

00:06:55 Speaker 2

So it can be a strategy not to touch at all, if they contained a lot of nasties, then you can get away from it

00:07:02 Speaker 2

assume that they are invalid in case of doubt.

00:07:04 Speaker 2

So as a mnemonic sentence you can say or remember, in A.G.B.

00:07:07 Speaker 2

everything that brings something is usually ineffective and therefore simply not fun.

00:07:14 Speaker 1

O.K., that is, the focus should not be on renegotiating A.G.B.s, but on renegotiating these S.L.A.s you just talked about afterwards and not taking them for granted, but on the contrary even as leverage to economically reduce the

00:07:30 Speaker 1

providers to make concessions.

00:07:32 Speaker 2

Absolutely, that's exactly where I would start, SLAs are central and maybe a step back, I can talk about a whole lot of contract points afterwards that you should think about.

00:07:45 Speaker 2

There is an investment decision with the customer who says, I buy this product or we are talking about rent here, cloud is rent, so I rent this product, there is the investment decision that has to be secured.

00:07:58 Speaker 2

i.e. how long is the contract term, how long am I sure at all, I'm doing a transformation project into the cloud, maybe I have to adapt processes.

00:08:07 Speaker 2

If the provider can terminate my contract after a year, then I have a huge transformation effort that I cannot amortize.

00:08:13 Speaker 2

So you want the provider to be available in the long term and you want to remain flexible as a customer, even be able to cancel as quickly as possible.

00:08:22 Speaker 2

This part

00:08:23 Speaker 2

service description and commercial framework, which is excluded from the A.G.B.

00:08:28 Speaker 2

Right or with certain nuances excepted, he just has to be transparent.

00:08:33 Speaker 2

So, if the price is not very friendly, but very expensive, then the law says nothing about it, as long as it is transparent.

00:08:41 Speaker 1

Now you have already teased several points, that was contract law in general, you said, ultimately also a piece of tenancy law that flows into it.

00:08:50 Speaker 1

You've talked about

00:08:51 Speaker 1

Data protection law as another point.

00:08:54 Speaker 1

There are other large right-wing blocs, I'm thinking of Data Act now, to consider.

00:08:58 Speaker 2

Definitely, you give me perfect keywords again, as always.

00:09:03 Speaker 2

Before I get to the Data Act, I would like to go back to this topic of Compliance with Law.

00:09:09 Speaker 2

This is also relevant for medical device manufacturers or customers, to ensure that the software maps standards.

00:09:17 Speaker 2

So let's put it neutrally,

00:09:18 Speaker 2

Standards that can be of a legal nature, quasi legal, regulatory norms customary in the industry.

00:09:25 Speaker 2

And to take a closer look, what does the provider actually agree to or if you are a provider yourself, what does the clause look like?

00:09:32 Speaker 2

Very simple clauses always mean that everyone abides by the law, but that falls short.

00:09:37 Speaker 2

You have to take a closer look.

00:09:39 Speaker 2

It starts with such simple things as commercial and tax requirements.

00:09:44 Speaker 2

Some industries are regulated in terms of their security and control systems.

00:09:49 Speaker 2

Banks and insurance companies could also go so far as to say, yes, a management that now puts a central application in the cloud, what does it have to do to meet its own due diligence obligations and then, of course, there is the large area of pharmaceutical and medical device manufacturers, which are again specifically regulated, and you at the institute are of course particularly full of knowledge and ideas.

00:10:12 Speaker 1

Yes, so maybe that's exactly what it will do with this

00:10:15 Speaker 1

field of medical device law.

00:10:18 Speaker 1

So, I think the listeners of the podcast know what is specific here now.

00:10:22 Speaker 1

Of course, we are now here in a software-heavy environment.

00:10:26 Speaker 1

This means that the usual requirements of the M.D.R.I.V.D.R.

00:10:30 Speaker 1

Of course, everything that has to do with software is used here.

00:10:33 Speaker 1

So, keyword 62 304 risk management, usability, I.T.

00:10:39 Speaker 1

Security, which is now so completely new

00:10:41 Speaker 1

has also been described, for example, knows about the new harmonised standard, 81001 indent 5 indent 1.

00:10:49 Speaker 1

But I think the listeners know that.

00:10:51 Speaker 1

What they may not always have on their radar are the difficulties that come with it, which are cloud-specific.

00:11:00 Speaker 1

So one example is the provider, for example from Diga, who uses a cloud service, he becomes the operator at the same time.

00:11:09 Speaker 1

Yes, that is, most manufacturers have

00:11:11 Speaker 1

The manufacturer's obligations on the screen, i.e. M.D.R.

00:11:15 Speaker 1

standards, which I have just talked about, but they do not always have on their radar the operator requirements that now go hand in hand with them.

00:11:22 Speaker 1

And that also has something to do with the fact that afterwards the enforcement is somewhere else.

00:11:27 Speaker 1

This is not even the fault of the managing authority, but it is suddenly the responsibility of the authorities.

00:11:31 Speaker 1

And these are things where I suspect that some providers can still sharpen up.

00:11:36 Speaker 1

A second point that we observe again and again, where the

00:11:40 Speaker 1

Medical device manufacturers who use cloud services are already in the definition of what is actually a medical device, because we have a special situation.

00:11:49 Speaker 1

So normal ones in quotation marks, medical device manufacturers just sell their products in large numbers, hopefully.

00:11:57 Speaker 1

In the cloud environment, we have an instance of N.

00:12:00 Speaker 1

equal to 1 as a rule.

00:12:01 Speaker 1

And now the question is, what is the medical device anyway?

00:12:04 Speaker 1

And if we now have such a huge stack,

00:12:06 Speaker 1

technology stack, yes, which starts somewhere at the bottom of the sheet metal and goes over X.

00:12:11 Speaker 1

virtualization layers and operating system layers and application server layers, then it is usually not so clear, or they have not defined it, where is the boundary between the runtime environment and the medical device.

00:12:26 Speaker 1

Yes, and this decision is extremely important, because everything that is part of the runtime environment is not subject to a 62 304, for example,

00:12:34 Speaker 1

but everything they take over and declare part of the medical device is the subject of 62 304 and then we suddenly have the topic of sub with us.

00:12:43 Speaker 1

And that means that if you add too much of this stack on the one hand, then the medical device changes, even though you haven't changed it yourself, because the cloud provider has changed something.

00:12:55 Speaker 1

Yes, and that would be a problem, of course, but the other way around, if you say, O.

00:12:59 Speaker 1

K., I'll leave it

00:13:00 Speaker 1

just define my own code as the medical device.

00:13:03 Speaker 1

Then the topic of risk management often becomes a bit more difficult to master.

00:13:07 Speaker 1

So maybe these are a few examples where we have cloud-specific medical devices, legal requirements that are not always easy to meet.

00:13:17 Speaker 1

But that as a short digression, we will return again.

00:13:21 Speaker 1

So we had now begun, or you had begun, to present to us this, this whole breadth of contract law, tenancy law,

00:13:30 Speaker 1

Data protection law, Data Act was just another point.

00:13:33 Speaker 1

Then you also addressed these other compliance issues.

00:13:37 Speaker 1

For example, you probably have G.

00:13:39 Speaker 1

M.

00:13:39 Speaker 1

B.

00:13:39 Speaker 1

H.

00:13:40 Speaker 1

law or the duties of the managing directors.

00:13:43 Speaker 1

Of course, there is a lot more, we can't discuss everything, but let's dive into a few areas.

00:13:50 Speaker 1

Let's start again with contract law.

00:13:52 Speaker 1

Yes, so there was tenancy law, did you already say, A.

00:13:54 Speaker 1

G.

00:13:54 Speaker 1

B.

00:13:54 Speaker 1

it was a topic for a very short time.

00:13:56 Speaker 1

What is there supposed to be

00:13:58 Speaker 1

Medical device manufacturers are also likely to pay special attention to other companies when they either draft their contracts or sign contracts from these cloud providers.

00:14:08 Speaker 2

In terms of contract, this tenancy law in itself is rather convenient for the customer, for the user, because strictly speaking, the provider must

00:14:19 Speaker 2

keep the product or service fit for use over the duration, over the service life that he promises, and thus he would basically have to follow all standards and norms.

00:14:29 Speaker 2

Yes, the legislator comes up with something nice again and then he is actually obliged to offer the product in such a way that it is marketable.

00:14:38 Speaker 2

Depending on which side of the table you are sitting on, whether you are with the provider or with the customer, you have to look closely at how the corresponding rules are formulated.

00:14:49 Speaker 2

That would be the first area, which I had already briefly talked about, compliance with law and then in relation to tenancy law.

00:14:56 Speaker 2

So I actually have such a permanent warranty to provide as a provider and as a customer I can even lean back a bit.

00:15:03 Speaker 2

You can also find in A.

00:15:05 Speaker 2

G.

00:15:05 Speaker 2

B.

00:15:05 Speaker 2

take something away from this strict warranty, one could say, but not much.

00:15:10 Speaker 1

So since I have an example, perhaps, so that I have understood it correctly,

00:15:14 Speaker 1

If, for example, the legislator were to follow suit, to address the issue of I.T.

00:15:18 Speaker 1

Security, which actually happens all the time, then you say, or is my understanding of what you're saying, the user of this cloud can assume for the time being, because the thing rents, that the person who offers these cloud services will then be able to use this I.T.

00:15:34 Speaker 1

security measures are actually taken into account.

00:15:37 Speaker 1

.

00:15:39 Speaker 2

That's how I would put it, of course, now we come to the old lawyer's joke, before the legal question is answered, it is asked who we are actually advising.

00:15:47 Speaker 2

From the customer's point of view, of course, I would propagate it that way and the provider sees it quite differently, he says yes, the NIS 2 directive, if it applies to you, is your problem.

00:15:57 Speaker 2

Yes, I'm just a cloud provider here, you just have to keep an eye on that, that has to be clear under contract law, that's just my petitem for now,

00:16:06 Speaker 2

For the customer, I would always say that the customer can expect that a product that comes onto the market reflects the applicable standards and is brought to market in accordance with the law.

00:16:18 Speaker 2

You can say that there are spheres of risk, which standards does a customer typically have to meet and which is more likely to be met by the provider.

00:16:26 Speaker 2

Yes, you have to find a clean demarcation, it has to remain reasonable somehow.

00:16:30 Speaker 2

This is often done in a somewhat simplistic way in the contracts.

00:16:35 Speaker 2

Availability would be a second important contract issue.

00:16:39 Speaker 2

We had talked about S.L.A.

00:16:40 Speaker 2

.

00:16:41 Speaker 2

Providers or manufacturers often offer so-called service level credits if availability is not reached.

00:16:49 Speaker 2

Sometimes they are so small that it's hardly worth putting someone to ask for a credit because the

amounts are simply too small.

00:16:57 Speaker 2

You then get back one percent of the monthly salary or something like that, no one sharpens the pencil.

00:17:02 Speaker 1

Yes, maybe just now

00:17:04 Speaker 1

Thinking about this, we have now had Skiron Confluence systems for these Atlassian products, i.e. those that are mainly used in development, that they were not available at the time and the first notified bodies have demanded concepts from their customers, i.e. the medical device manufacturers, on how they want to ensure that their processes still run in compliance with standards.

00:17:29 Speaker 1

So an example would also be customer feedback system, if this

00:17:33 Speaker 1

systems are not available.

00:17:34 Speaker 1

Yes, so that means that the one percent monthly reimbursement doesn't help them at all, they are really in legal trouble, because to say, yes, I have a system that backs up virtually everything, yes, or that ensures that there are no legal problems if my service provider fails, will often mean that you have to

00:17:54 Speaker 1

ultimately has a redundant system and you have to ask yourself, OK, what's the point of the cloud then?

00:17:59 Speaker 1

So this as, so to speak, as an agreement with what you have just said, that these compensations are completely unsuitable in most cases to really compensate for this damage.

00:18:09 Speaker 2

Definitely, especially if it is perhaps even such a tiered delivery system, in which there is another infrastructure behind the actual provider that he himself does not master, but which he also buys.

00:18:23 Speaker 2

strictly speaking, he must then also pass on the duties in his contractual relationship, in his purchasing relationship.

00:18:29 Speaker 2

It is also advisable for customers to agree that this will be disclosed.

00:18:35 Speaker 2

Yes, how far does the fulfillment of duties actually go in your supply chain?

00:18:38 Speaker 2

This is a tiresome topic, but if you want to fulfill your own duties, there is probably no way around it.

00:18:44 Speaker 2

A great concern of my heart is always data access and data release.

00:18:50 Speaker 2

I want to go back to the

00:18:53 Speaker 2

Data Act.

00:18:54 Speaker 2

But from a purely contractual law point of view, from painful experience for clients, I have to say that it is important to be able to stipulate a contractual right, at any time and without reservation, no rights of retention, no special remuneration, to be able to obtain a data extract in the appropriate format, at any time.

00:19:16 Speaker 2

Yes, you can talk about costs, of course, you can buffer it a bit,

00:19:22 Speaker 2

but from the case law and the current legal situation, the instruments to get his data back are inadequate.

00:19:31 Speaker 2

So such a very clear claim for restitution, that comes with the one with the Data Act, it gets better there.

00:19:38 Speaker 2

But now it is necessary under contract law to inscribe this clearly.

00:19:42 Speaker 1

So that would be another tip on what should be regulated, yes in the area of contract law, so this topic of surrender, yes availability we have just discussed, these rental stories

00:19:52 Speaker 1

and what actually belongs to it, what can you assume, these are important aspects that should be regulated under contract law.

00:19:59 Speaker 2

Definitely.

00:19:59 Speaker 1

Then let's dive into the next area of law, data protection law.

00:20:03 Speaker 1

This is also a never-ending topic, especially if you now think in the direction of American hyperscalers, there is a back and forth with Schrems 1 until, I don't know where we have arrived in the meantime.

00:20:16 Speaker 1

Help us out

00:20:17 Speaker 1

What should they pay attention to now, especially companies that want to store sensitive data such as health data?

00:20:25 Speaker 1

What would be your tip?

00:20:27 Speaker 2

So, the tools for mapping data protection supply chains are probably familiar to your listeners.

00:20:33 Speaker 2

Yes, these are the classic agreements on order processing towards their own customers, which potentially import health data into the system, you need

00:20:45 Speaker 2

explicit consent, the instruments that work with simple personal data, balancing interests and so on, don't work so well.

00:20:56 Speaker 2

So this set of instruments is definitely to be used.

00:20:59 Speaker 2

Personally, I am actually a fan of technical-organizational data protection, I also do data protection at the university.

00:21:07 Speaker 2

Paper is patient and it's always nice to have the right contracts, but risk-appropriate

00:21:13 Speaker 2

technical measures, with all the disadvantages that you cannot search on encrypted data and so on.

00:21:19 Speaker 2

But to turn up the standard first, that would be my first advice.

00:21:24 Speaker 2

You had the topic U.S.

00:21:25 Speaker 2

transfers.

00:21:27 Speaker 2

I think it took on a bit of a life of its own in the legal discussion.

00:21:32 Speaker 2

Schrems 3 is expected, yes, is already halfway through, and it is always about these transatlantic agreements

00:21:41 Speaker 2

between the EU and the US, for various reasons that would probably bore listeners now.

00:21:50 Speaker 2

But the latest agreement is the EU-USA Data Privacy Framework, there is the successor agreement on the Safe Harbour and the Privacy Shield, both of which have been overturned by the European Court of Justice and have been improved by creating certain mechanisms with regard to legal protection.

00:22:10 Speaker 2

for E.

00:22:11 Speaker 2

U.

00:22:12 Speaker 2

Citizens, for example, who continue to be criticized.

00:22:14 Speaker 2

So you can actually set the clock that the European Court of Justice will say something about it again and it is not unlikely that it will also be overturned, but don't panic.

00:22:25 Speaker 2

In the meantime, when the first 2 overturns of these agreements happened, they also made do with so-called transfer impact assessments and the standard contractual clauses.

00:22:38 Speaker 2

It is a

00:22:39 Speaker 2

maybe a good idea anyway and a good advice to providers and also users to make such agreements with an assessment.

00:22:48 Speaker 2

What does this mean, what risks do we have?

00:22:51 Speaker 2

Anecdotally, I can perhaps tell you, even the cautious Swiss, I think in the canton of Zurich now after a 2 expert opinion

00:23:02 Speaker 2

, they then decided to also use U.S.

00:23:05 Speaker 2

Clouds.

00:23:07 Speaker 2

Statistically, you have thought about how often it happens now that the N.S.A.

00:23:11 Speaker 2

would ask for certain data releases from Zurich cantonal citizens and then found out that it would be the case once in 1500 years and then we said, we can take this risk.

00:23:24 Speaker 2

So you can also remember here that data protection is not black and white and not fundamentalist, but pragmatic.

00:23:32 Speaker 2

But it has to be well documented and thought through, and if you do these impact assessments and then have a proper, orderly process, then as a rule nothing happens.

00:23:41 Speaker 1

O.

00:23:42 Speaker 1

K., I'll summarize very briefly, on the one hand you gave the all-clear, also with Schrems 3, that this is somehow a manageable risk for the manufacturers, but on the other hand you also said, please be precise in your agreements with your customers.

00:23:56 Speaker 1

In other words, that this explicit consent actually exists, number 1 and number 2.

00:24:01 Speaker 1

you had said, make sure that you have actually ensured the technical, organizational measures, so that you are no longer so dependent on how well they meet their data protection requirements.

00:24:13 Speaker 1

Did I summarize that correctly?

00:24:15 Speaker 2

Exactly right and the last point is this agreement along the supply chain when we go to other geographies and there too you have to say that the hyperscalers now also offer E.

00:24:29 Speaker 2

U.

00:24:30 Speaker 2

or Germany Clouds

00:24:30 Speaker 2

then with the one with the small footnote that of course accesses are theoretically still potentially necessary or possible through the U.

00:24:39 Speaker 2

S.

00:24:40 Speaker 2

Mothers who can also be enforced.

00:24:42 Speaker 2

But that brings us back to this topic, which I addressed, and you can use transfer impact assessments to create a file situation, let's say, that seems manageable.

00:24:52 Speaker 1

Mhm, then I would say, let's take a closer look at the third and perhaps last topic.

00:24:57 Speaker 1

Data Act was a very short topic.

00:25:00 Speaker 1

What are the most important requirements that you should know?

00:25:03 Speaker 1

What would be your tips to fulfill them?

00:25:06 Speaker 2

Exactly, Data Act is probably one of the hottest topics at the moment.

00:25:13 Speaker 2

What is it about?

00:25:14 Speaker 2

Basically, it is not about personal data, but about machine data, which is used by I.O.T.

00:25:22 Speaker 2

devices, so that those involved in the generation of this data

00:25:29 Speaker 2

These are usually the users of such products, that they also get access to the data.

00:25:35 Speaker 2

The EU expects this to lead to a major upswing in data-driven business models and it would not be the EU if it had not enacted a regulation to spur this upswing, namely the EU Data Act, which is to be implemented by September 2025.

00:25:54 Speaker 2

And it's about this big issue of access.

00:25:57 Speaker 2

But

00:25:57 Speaker 2

we have already dealt with this in the other podcast, also included in this Data Act, is a chapter that is aimed at cloud providers and today we are in the cloud area and there is a clear perspective of regulation, namely to break the so-called vendor lock-in.

00:26:17 Speaker 2

So you want to have short-term notice periods, you want the possibility to design standards and data in such a way that

00:26:26 Speaker 2

customers can also change providers at short notice.

00:26:30 Speaker 2

Specifically, we have a two-month notice period, which is provided for in the Data Act and, for example, an obligation on the part of providers to help customers switch free of charge.

00:26:42 Speaker 2

Corresponding formats, i.e. exportable data formats and digital assets, as stated in the Data Act, must therefore be provided in such a way that the transfer is also possible.

00:26:55 Speaker 2

of course, this is not in the interest of the cloud providers.

00:26:58 Speaker 2

I'm curious to see how this will work commercially, because the long-term investment security, what the providers like to have, that they can say, we have a 10-year contract with X.

00:27:08 Speaker 2

is then always under this sign that the Data Act just says, well, it's nice, but after 2 months, with 2 months notice, the customer is out.

00:27:19 Speaker 1

What would then be the concrete recommendations that you would give to medical device manufacturers or other companies?

00:27:26 Speaker 2

Well, first of all, you have to, you can sit back and say that this is a legal regulation.

00:27:32 Speaker 2

By the way, it is still unclear how it will actually be enforced now.

00:27:35 Speaker 2

Are contracts with long-term contract terms now null and void?

00:27:40 Speaker 2

According to the current opinion, no, but it is first of all an obligation of the providers to provide for these rules and customers should insist on them.

00:27:47 Speaker 2

to say, dear provider, the Data Act says 2 months, you say here minimum term 5 years, we have to talk about it.

00:27:54 Speaker 1

Then your recommendation is actually to be aware that you have another chance here if you want to get out of the contract.

00:28:01 Speaker 1

So use this lever and otherwise the feet will shut down.

00:28:04 Speaker 2

Definitely and I want to use it in such a way that I address it in the contract discussion in the exam.

00:28:09 Speaker 2

Yes, it has to, it has to be on the table.

00:28:11 Speaker 2

It doesn't really help if the accident has happened afterwards and

00:28:15 Speaker 2

they say that the Data Act stands and there is no real enforcement mechanism behind it yet.

00:28:21 Speaker 1

Yes, if I have such a lawyer here, what else would you need to know about what is in the E.

00:28:26 Speaker 1

U.

00:28:27 Speaker 1

There is something new about what is currently being sizzled.

00:28:31 Speaker 2

Yes, hopefully we'll be doing a podcast about the K together soon.

00:28:34 Speaker 2

I.

00:28:35 Speaker 2

regulation, the NIS 2 Directive, which is about cybersecurity, which is very important, then there is the Cyber Resilience Act,

00:28:43 Speaker 2

which is also aimed at companies that need to take increased resilience precautions, yes, in order to bet-

ter master their cybersecurity risk management.

00:28:52 Speaker 2

If I remember correctly, in the von der Leyen Commission period of 5 years, we have a total of 113 legislative projects and projects in the digital sector alone.

00:29:01 Speaker 2

So I could talk about it for the next half hour, but I'll spare you and your listeners.

00:29:06 Speaker 1

O.

00:29:07 Speaker 1

K., but that means that the topic of cybersecurity, that is now still

00:29:10 Speaker 1

are gaining in importance.

00:29:11 Speaker 1

That means we need another podcast about it, where we dive in again.

00:29:15 Speaker 2

Absolutely, very gladly.

00:29:16 Speaker 1

Yes, then perhaps at the end the question, what do you advise companies to do now in concrete terms and how can you help?

00:29:23 Speaker 2

Well, first of all, read the contracts carefully.

00:29:26 Speaker 2

So that's my advice.

00:29:28 Speaker 2

Of course, you think these are A's now.

00:29:30 Speaker 2

G.

00:29:30 Speaker 2

B.

00:29:30 Speaker 2

and I put them aside somehow.

00:29:32 Speaker 2

I had also said at the very beginning that it can also be a strategy that A.

00:29:36 Speaker 2

G.

00:29:36 Speaker 2

B.

00:29:36 Speaker 2

consciously put it aside.

00:29:38 Speaker 2

because very disadvantageous clauses are invalid anyway.

00:29:42 Speaker 2

But you should think about what they are.

00:29:45 Speaker 2

So this juxtaposition of lease contract law and what is then in the cloud contract, that's the least you have to do, to check your own compliance along the supply chain, to make sure that the standards and norms that you have to provide and deliver yourself are also mapped in the cloud installation.

00:30:06 Speaker 2

And otherwise I am always grateful for illustrative material.

00:30:09 Speaker 2

I am also writing a chapter in a lawyer's handbook on this.

00:30:12 Speaker 2

That's a bit of a bible for the IT lawyers who want to become specialist lawyers.

00:30:17 Speaker 2

I am allowed to write the chapter cloud and if you would like to send me a contract and have questions about it, you are also welcome to contact me.

00:30:25 Speaker 1

That's a great offer, yes.

00:30:26 Speaker 1

That is, if you get help.

00:30:28 Speaker 1

So, it's a win-win situation, I understand.

00:30:31 Speaker 1

You already have the input for your book and the companies that contact you,

00:30:35 Speaker 1

get an assessment of the contracts.

00:30:38 Speaker 1

Helping people to help themselves is great.

00:30:41 Speaker 1

Exactly, and that's what we always want to do here in the podcast and with that I thank you, Marc, for these further insights into the big topic of cloud law.

00:30:51 Speaker 2

Yes, thank you very much, so if you don't ask, you don't get, you can say, so don't just accept anything just because it's cloud contracts, but look at it, check it and then move on.

00:31:03 Speaker 2

Thank you very much for the invitation.

00:31:04 Speaker 2

It was fun.

