

Requirements for EU Authorized Representatives

With Margarita Rozhdestvenskaya , Prof. Dr. Christian Johner

Transcript

00:00:05 Speaker 1

Medical Device Insights, a podcast by the Johner Institute for Medical Devices, Manufacturers, Authorities and Notified Bodies.

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With the M.D.R., which is now coming into force, we have some requirements that also affect the so-called plenipotentiaries.

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And in this podcast

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let's take a closer look at what these requirements are now, which I also compare to the M.D.D.

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in this regard and whether you absolutely need this role now or whether it would also be possible to outsource this role.

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And I called my colleague Margarita to explain it to us, because she has quite a lot of experience in this area.

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Margarita, did you want to briefly explain to us and our listeners who you are or what you have already done in this context?

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With pleasure, Kristian.

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Thank you.

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Margarethe Rasch-Destinski, my name.

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I am a graduate economist by training.

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I completed my studies at the Technical University in St.

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Petersburg.

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For the last 9 years, I have headed the European representative office of a non-European manufacturer of an active medical device and was on his behalf to provide the authorities within the EU

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as a contact person.

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In addition to providing the necessary documentation of the notification obligations and reporting obligations, I was also responsible for conducting post-market clinical follow-up studies.

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At Jona Medical, I support our customers as a certified auditor for QM systems according to ISO 13485 in the lawful placing of medical devices on the market in Europe

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also by taking on the role of safety officers or persons responsible in the future and writing and checking the technical documentation as well as implementing the Q.

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Systems.

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Yes, the first question that naturally arises here is, who needs an authorized representative at all?

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You could almost say, who should listen to this podcast.

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Margareta, which companies

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must have such a person.

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Can you give us a brief explanation?

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All medical device manufacturers based outside of Europe must appoint an authorized representative based in the EU to meet the requirements for placing medical devices on the market in Europe.

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For these manufacturers, the authorised representative in the European Union plays an essential role.

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This can be both a natural person and a legal entity.

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and now you say that all those who are outside the EU, the Swiss also count outside the EU.

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To date, medical device manufacturers from Switzerland have been able to participate fully in the EU internal market.

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The basis for this is the mutual recognition agreement between the Swiss Confederation and the European Union.

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If this agreement is in force by the date of application of the MDR, i.e. 26.

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May 21, will not be updated,

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must all medical device manufacturers from Switzerland also comply with the requirements for the third-country medical device manufacturer from the beginning of the applicability of the MDR?

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K., so it's not really good news for them.

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That means that if they don't agree, then they do indeed need an E.

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Authorized Representative.

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Yes, that's not so good.

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Yes, but maybe let's talk about what such a

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Authorized representative does everything, maybe even again, which is the sense, because the M.

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and you have to say, even the IFA, who actually had or why they were on this role and you said yes, it can be a person, a legal person or a natural person, why the regulations insist on it like that.

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The regulation clearly expresses the wish that the authorised representative should create an additional supervisory authority.

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This is intended to ensure that the monitoring and control of the medical device manufacturer from a third country as well as the corresponding surveillance and vigilance activities after placing on the market have been carried out appropriately.

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Starting with the verification of the conformity of the technical documentation,

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until the fulfilment of vigilance obligations.

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In addition, the authorised representative is jointly liable with the importer and the manufacturer.

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Mhm, so I hear 2 main reasons now.

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One thing, you want to be able to grab someone by the slurry, that I can't the manufacturer, who is now somewhere in Asia, for example, can escape it.

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And the second thing I've heard now

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is that this person is also a checking authority, among other things for the technical documentation, you just said.

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I think we should perhaps talk about liability again in a moment, but let's get back to the question.

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Yes, I think you've already mentioned what he's doing in the part now.

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The tasks of the EU Representative are set out in Article 11 of the MDR.

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These must be recorded in a written mandate.

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The tasks of the authorized representative can be roughly divided into 4 fields: On the one hand, it is about checking that the declaration of conformity and the technical documentation have been prepared and, if necessary, that the manufacturer has gone through a corresponding conformity assessment procedure.

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On the other hand, the authorized representative must check that all registration regulations have been complied with.

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The Authorised Representative shall be entitled to

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in official audits and product tests.

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Furthermore, he checks that all surveillance data is placed on the market and vigilance activities have been carried out.

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Mhm, maybe we will now go into more detail about a 2 of these points.

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1 you said, he has to have the documentation ready.

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So it is said that he really has the files on his table, so to speak, and can then put them on the table at any time

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to the authorities is what is meant.

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The legislator says that the documents must be accessible throughout.

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I would say that a copy of the technical documentation of the EU declaration of conformity and, where applicable, a copy of the relevant certificates issued must be available to the EU Representative.

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OK, that means he then has full access to all this confidential documentation, which the manufacturers don't necessarily always like to give away.

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Can you say that?

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That's absolutely true, Christian.

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The EU Authorised Representative has full access to all confidential information contained in the technical documentation.

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Let's get back to the fourth point, namely post-market monitoring or vigilance.

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You had already indicated that the person

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must participate in these vigilance processes, i.e. must also report or forward the feedback from the field to the manufacturer.

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Does the authorised representative also have to actively carry out Post Market Surveillance himself?

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So he himself has to proactively search authorities, databases, for example.

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This is not stated in Article 11

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But because the authorized representative is jointly and severally liable, it would definitely be recommended.

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That is, we have now talked about the 4 points that such an authorized representative has to take care of.

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What has changed if we compare it again between M.D.D.

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and M.D.R.?

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Compared to the M.D.D.

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many changes have taken place.

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On the one hand, the tasks and duties of the E.U.

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Plenipotentiaries in 2 permanent articles, Articles 11 and 12, and on the other hand, by the fact that the E.U.

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It is in his interest to verify the conformity of all activities and all documents.

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K., that means that he will really, as you actually said at the beginning, become the

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Testing authority and in my opinion this also increases the requirements for competence, because if the person has to check this, the conformity, then he should now have a clue about the product and not just then be a nudge of the documents.

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Does this also make the authorized representative personally liable?

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That's absolutely true.

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The information for this can be found in Article 11.5

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If the manufacturer, who is not established in the EU Member State and has not complied with his obligations under Article 10, the authorised representative is legally liable on the same basis as the manufacturer, with the latter jointly and severally liable.

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Mhm, and then everything is part of it.

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This includes the corresponding administrative offenses and, in the worst case, imprisonment.

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I think that's exactly what the legislator naturally wants to have, that no one

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You can steal out of it, so to speak, but you always have one person and that is now in this case the EU Plenipotentiary.

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For companies that, as you just said, are outside the EU or manufacturers outside the EU, they have other roles that they have to have.

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There is also the role of the trader or the role of the importer.

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Do they have to be different, yes, of course, or legal entities or can they be

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Manufacturers outside the EU say, that's everything for me, so to speak.

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So I have a natural legal person who is a dealer and importer and authorized representative.

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Both the distributor and the importer can take on the role of the European representative.

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However, it replaces that the person has the necessary regulatory knowledge and it is probably also necessary to consider the economic sense, because otherwise you will become economically dependent.

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Absolutely and there is another point when I think back to what you said, you won't necessarily want to overload a dealer or importer with all his technical documentation.

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Yes, if we are talking about the economic aspect right now, so to speak, can you do something like that

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outsource, such a role.

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You've been doing it for many years and you're still doing it.

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So can you give us an idea?

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So, when is it allowed?

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In any case, it is advisable to find a competent partner to take on the role.

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As Jona Medical and a wholly owned subsidiary of Jona Institute, we offer our customers the opportunity to perform the functions prescribed under the regulation, as a manufacturer, as an authorized representative or even as a person in accordance with Article 15 responsible for compliance with the regulation

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regulations.

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Mhm, that means you can outsource it, I hear that from your lines, there is no restriction that you give this role to someone else.

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That's true, the role can and may be taken care of, but the prerequisite for this is that the authorized representative can fulfill his obligations by having the necessary regulatory competences.

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If you are now faced with the choice of a company, an authorized representative

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yes, to choose.

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What would be your recommendations, what should such a company pay attention to?

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First and foremost, of course, is competence, which is the basis for smooth cooperation and fulfilment of all legal requirements.

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In the case of our company, taking on the role of European representative is within the scope of our certification.

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That is, you can say,

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means reliability, process quality is therefore crucial that you can simply rely on these communication channels to work, with the manufacturer, with feedback from the field, with the authorities.

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And if someone has certified it, of course, you simply have a higher probability that it will work exactly as promised.

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If I hear you correctly and other arguments that you have already brought up, must of course be an absolutely trustworthy partner, because you can certainly also

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must reveal.

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Yes, Margareta, thank you very much for giving us an insight into this world of EU plenipotentiaries, which is also a world of its own.

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I'm happy that you were available to us because you simply, as you said earlier, you have many, many years of experience.

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Thank you very much.