Johner Institute

Barcode Verifier—a must-have for all medical device manufacturers?

With Wilfried Weigelt, Prof. Dr. Christian Johner

Transcript

00:00:05 Speaker 1

Medical Device Insights, a podcast by the Johner Institute for medical device manufacturers, authorities and notified bodies.

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The M.D.R.

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is getting closer and closer, and with it the obligation to provide medical devices with a U.D.I.

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we were already able to experience how important this topic is for the manufacturers of medical devices last year.

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So over 750 people in the webinar with Luca Salvatore on the topic of U.D.I.

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What we didn't talk about at the time was the question of how we have to raise these U.D.I.s afterwards and how do we have to ensure that they have now been applied in the right quality, because that also has to be proven in the end.

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And how to check something like this and what regulatory requirements there are, I would like to talk to Mr. Weigelt about that today.

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Mr. Weigelt, could you briefly introduce yourself to our listeners, please.

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Yes, my name is Wilfried Weigelt.

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I work for the company Reelektronik G.M.B.H.

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in Mühltal and am responsible for the area of code checking devices, optical measuring devices for measuring matrix codes and barcodes.

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And I also have areas of responsibility that fall within the name area of standardization.

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This means that I am a member of the DIN Standards Committee, which is responsible for the coding, as well as for the data structures used in U.D.I.

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as well as then correspondingly for the, the ISO committee, which is ISO E.C.J.T.C.

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One S.C.

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31 Working Group One.

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And this working group 1 is responsible for data matrix codes for undercode types, i.e. the so-called simulogi standards and the quality standards that are defined by the U.D.I.

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and M.D.R.

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targets are achieved.

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On the one hand, this means department heads at Real Elektronik GmbH and on the other hand, the area of standardization, standardization at DIN and ISO.

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We have exactly the right spell with the podcast.

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Yes, if we now talk about this U.D.I.

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they have to be applied somewhere on these products.

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I imagine this to be a bit easier with the software, like perhaps on any physical devices, that is, medical devices or maybe even some plastic parts.

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I could imagine that a lot can go wrong.

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What could go wrong if you have such a U.D.I.

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what the manufacturer then has to watch out for so that it doesn't happen.

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There are various possibilities.

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The easiest option you have is to use the wrong type of code.

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We usually have a data matrix code.

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For example, you could now apply an ACC code or a QR code, which is usually not read because the scanners have switched off this type of code.

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The second thing that can go wrong is the content specifications.

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That is, data is in a certain sequence

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according to these ISO standards and according to the requirements of the Itch Entities into the codes and if this structure is not adhered to, then you can't clearly recognize and read out an article number, for example, or you can't reasonably recognize or read out a date of manufacture or a batch or a serial number.

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These would be substantive answers.

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The other is the questions of the substrate, i.e. what do I mark on?

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Is it plastic, is it metal, is it a label?

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if the structures and these substrate properties are unfavorable, then it may no longer be possible to distinguish the printing or the marking from the substrate.

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This then leads to a problem of optical and physical reading ability.

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And in the printing system or marking system itself, of course, you can also make mistakes by setting these systems incorrectly, configuring them incorrectly, operating them incorrectly, using the wrong inks, using the wrong ribbons in thermal transfer printing.

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So, there are a whole range of ways to make mistakes.

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What would be the consequences of making these mistakes?

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Some of them have already hinted at a bit, but I don‘t think all of them yet.

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The consequences would be: I read a code and I can‘t do anything with the content if the data structures are wrong.

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The other consequence would be that data may be read incorrectly, i.e. that incorrect data is read in

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And the 3.

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The consequence would be that the necessary reading efficiency might not be achieved.

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Especially if you have components or products with high throughput rates, with large quantities and you have to read them quickly, then you will get a read rate of maybe 90 percent.

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And with many parts, 1000, 2 or 3000 parts, a 10% non-read rate can be fatal for the optimal production process.

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And so you get wrong data, no data at all.

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no reading or insufficient reading efficiency.

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How can it happen that the data is not applied correctly?

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So, of course, that you do it wrong in terms of content, I think that's in the sovereignty of the manufacturer, so to speak.

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But how can it happen that the label is not really legible afterwards, so to speak, because it is more distorted or because it doesn't have enough contrast and so on.

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If now

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And metal material is used, i.e. an O.P.

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cutlery is labeled as an example, then I have, for example, highly reflective materials.

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Or I have materials that are brushed or have a surface texture structure in some form.

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If that's the case, then you can compensate for it to some extent, but not to some extent.

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And such structures interfere with the recognizability of the code, so to speak.

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This usually leads to a non-read rate or non-reading if you go into these physical effects.

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And the other aspect is either the substantive aspect.

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So let's assume that the code can be read physically, but it cannot be read correctly in terms of content.

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Then it would be more a matter of layout.

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So, how do I create my code, my label layout, and on the other hand, a question of the software, whet-

her it is able to guide the user in the correct

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Implementation of the required data structures according to GIS One, HIBC, ICTBA, i.e. Ethian Entities.

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And that is abandoned, but not always given.

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You have just described, already in the introduction, that you are not only someone who is distinguished by this high level of expertise due to your membership in old standards committees, but is also employed by the company as a department manager who

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that deals with devices or that manufactures that identifies exactly such problems.

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And if I understood correctly, these are the so-called verifiers.

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Could you briefly describe to us what such a verifier can really detect?

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So, what types of problems?

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‚N Verifier makes 3 different categories of checks,

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The first category you have there is precisely these code properties and layout properties.

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So, do I have the right structure, do I have the right type of code, as long as the default is correct?

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The second category you have there is everything that has to do with reflections and contrasts.

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So, do I have enough contrast?

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Are the distributions of the brightness of matrix cells that are supposed to be dark uniformly black or are the white matrix cells uniformly white?

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as an example, the contrast is sufficiently large and the third category is the print accuracy, i.e. is such a code distorted in some way.

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So distorted into the X-axis, distorted into the Y-axis, or worse, distorted unevenly.

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This means that individual matrix cells are of different sizes and differently displaced, and this then has the consequence that it is correspondingly difficult to read.

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And these 3 categories

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Code properties, layout properties as one category, the second category reflection contrast properties and the third category, the print accuracy properties, are metrologically checked by such a verifier.

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How does he do that?

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So, how does he manage to identify all these different problem classes?

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In principle, it's relatively simple, you take a picture first, so take a photo,

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And this photo is then evaluated according to standardized algorithms.

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So, you recognize this one.

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code.

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The code is decoded.

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Once I have decoded the code, then I know what kind of code it is.

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If I have made certain properties and presets, then the wrave expects a certain structure, structured content, a certain data structure and the other properties, contrasts and printing accuracy,

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There, in turn, there are test standards that now say how good such a code must be or what is being tested.

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So, a test methodology ISO EEC 15-15 for the printed codes and the ISO EEC 29-158 for the cover marked codes.

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And now, for example, there is Datamatrix, the so-called simulgi standard ISO EEC 16022.

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And they now determine the properties.

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So, what contrasts do I need to achieve?

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how much can my code be distorted and what is the disk structure that is lower than that of the data structure according to Issue Agency requirements, such as G.

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S.

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One or H.

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I.

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B.

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C.

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You have already talked a lot about norms.

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Let's just go into this area, including regulatory requirements.

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On the one hand, the question of whether the standards now concern the manufacturers of such verifiers and perhaps the second question, if I may push it right after,

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What other requirements do manufacturers now have to meet in this context?

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There are 2 things or 2 levels.

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On the one hand, I have equipment technology.

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The device technology is an optical measurement technology and this optical measurement technology is subject to certain minimum requirements and measurement tolerances and these are defined by ISO standards.

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There is an ISO standard 15426 hyphen 2 and it now specifies how exactly such a

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device and what properties, measuring properties are checked.

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This applies to the device technology, i.e. control of the measurement properties.

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And the second category, these are the standards that now determine, what kind of code type do I have, data matrix, as mentioned, 160 22 and then the methodology of quality control of the barcode or the 2D code, the ISO EC 15 415 29 158 for DPM.

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The M.D.R.

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as well as the U.D.I.

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stipulate that certain quality characteristics or quality assurance measures must be fulfilled by the manufacturer.

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These, in turn, refer to the American U.D.I.

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system to an ISO standard 15459 and these in turn determine, such as a G.S.

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One, H.I.B.C.

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and similar be registered and defined as an Asian Entity or Agency.

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In other words, in this way, the Ethian Agencies entities are implicitly included and included in M, so to

speak.

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D.

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R., with the European one, it is similar.

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They call these Ethian Entities directly and also directly demand that the requirements set by the Ethian Entities must also be implemented in quality assurance.

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And the Ethian Entities or agencies themselves, they use exactly these standards,

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namely the Data Matrix standard 16022 and the quality standards and thus determine what the properties of the coding should look like as a defined quality requirement.

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Can you say that these are 3 areas, so to speak, what comes directly from the legal level.

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Yes, you have to work with these issue entities, so to speak, yes, for example, then we have the requirement for the code or for the representation of the code, so to speak, and then we have a group of standards, so to speak, which

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takes care of checking whether everything has worked correctly now.

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Is this summary correct?

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Roughly, there is another aspect, and that is the data structures.

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The American specification quotes the ISO E.C.

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15 459 is a series of 7 or 8 standards, which specify exactly how the whole thing has to be structured.

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While the M.D.R.

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it's just up to

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vice versa and that means they first name the Asian Agencies and they in turn work with these ISO standards, the same as with the Americans, who now set the basic criteria for the data structures.

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And on the other hand, I simply have the Data Matrix as a data carrier, how it works.

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These are so-called simulogi standards 16022

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and the quality properties or quality control can now be understood across code types.

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This applies not only to the Datamatics, but also to other code data, i.e. ISO EEC 15 with the 15 when I print on labels as an example and the ISO EEC 29 158 when I mark away with the laser, for example, on a plastic part or on a metal part or also mark with the inkjet on a substrate, which does not correspond to a label, but is more critical.

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Mhm,

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With all the standards, the question arises, can a manufacturer still check this in a meaningful way without a verifier?

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Probably difficult.

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Of course, you can do that by going here now, for example, and buying a microscope, a measuring microscope and now looking at the code under this measuring microscope and assessing the individual properties, more or less manually.

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Theoretically, this is conceivable, but the effort is probably not really sensible in relation to the costs that such a verifier now entails.

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In the measuring microscope will probably be more expensive than a verifier, probably at least high-quality ones.

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And the manual effort that has to be made and the know-how that you have to have in detail, most manufacturers will not have that in this form and will not be able to acquire it in a meaningful way.

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From this point of view, a verifier is probably

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the cost-optimized solution to carry out such a quality control, as opposed to such a manual method with a measuring microscope.

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Mhm, can you give us an order of magnitude and maybe give us an idea of it in this context, does it make sense for a manufacturer to buy something like this or is it rather what you can borrow, so to speak, if necessary?

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What would be your recommendations?

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So, costs of such a verify, that is in the range of 6000 to about 10,000 euros, depending on the equipment and configuration and related to the measurement task.

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If you are now, let's say, a very small-scale manufacturer who has very few products, has few special products, then it may not make sense to set up such a device, but you buy the service of measurements, which you can then perhaps buy for 100 or 200 euros for some measurements.

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Renting would also be possible, but that is rather atypical in this area, i.e. leasing, for example.

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Ah, that's interesting.

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Yes, I have the feeling that you have opened a whole door for us into the new area, which I think many people don't even know yet, and I think the multitude of standards that you have just mentioned here make it clear that it is good to rely on someone you can rely on.

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and that you shouldn't try to check everything again by hand, but that the use of such tools probably makes sense after all.

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In any case, this makes sense, especially since afterwards the whole system throughout Europe and the U.S.A.

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and that everything is based on the same standards.

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Anyone who uses an incorrect encoding, an unreadable encoding or incorrect data structures

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can be fatal under certain circumstances, especially if it is sensitive products that are associated with high risk classes.

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Yes, I would say that this is a complex topic and that's why I will publish Mr. Weigelt's contact details in the show notes or below the article or a link to his website and then you can contact him directly and find out about the further details of verifiers, the regulatory requirements

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maybe then to really talk about the use of such a product.

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Mr. Weigel, thank you very much for being with us.

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Thank you very much for the invitation and thank you very much for the interview.