Johner Institute

From the World of Electrical Products: Whitness Testing and Descriptive Reports

With Beat Keller, Prof. Dr. Christian Johner

Transcript

Transcript

00:00:05 Speaker 1

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

00:00:19 Speaker 2

At the moment, all energy and attention is on MDR, but we want to broaden the view a bit today and also beyond

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Des Atlantic to see what's new there or what you have to consider if, for example, you want to put medical products on the market there.

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And I have invited Beat Keller, who may introduce himself very briefly, so that we all know who you are and how you are in this context.

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Yes, thank you very much, Christian.

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As you said, my name is Beat Keller.

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I am responsible for the company I.M.T.A.G.

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in Switzerland for the area of regulatory, quality assurance.

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and in this context, all the verifications of the devices that we develop for our customers at IMT, which are carried out and ultimately also have the appropriate stamps to be placed on the market.

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What kind of products maybe, I think that's quite interesting, you develop, for example.

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So we don't have any products at IMT AG ourselves, but we develop all kinds of large manufacturers of medical devices for you, which is actually the

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Main part at the moment is.

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From ventilation to anesthesia, ophthalmology, we actually have the whole range of medical devices that we are allowed to develop.

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And also, and with that, I think, you can also talk about the topic in the U.

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S.

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A.

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or creates the conditions for these products to be sold in the U.

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S.

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A.

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come into circulation.

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Yes, and that, I think, brings us to the topic.

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Maybe we should now look at it again from the space point of view, what do you have to do to create a

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Product and I deliberately say product and not medical device only in the U.S.A.

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on the market.

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It's similar to Europe, we have very different regulations.

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Somehow one of them in Europe is the E.M.D.R.

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and it is similar in the U.S.A.

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On the one hand, we have the medical device approval via the F.D.A., where we have already heard something a few times in the podcast,

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But there are also many other approvals.

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If I have a radio module in it, I need an F.

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C.

00:02:30 Speaker 3

C.

00:02:31 Speaker 3

Admission.

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And if I want to plug the medical device or the device in general into the socket, I also need a so-called N.

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R.

00:02:39 Speaker 3

T.

00:02:39 Speaker 3

L.

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Mark, i.e. a Nationally Recognized Testing Laboratory Mark, which says that the thing is electrically safe and can therefore be plugged in.

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So, as you just said, we have in Europe so wanted the medical devices

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product-specific, yes, approval procedures as well as the, I would like to call it, feature-specific ones.

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Yes, so if I may now call electricity a feature, there is also some.

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Which, I think in the field of medical devices, regulations, many people are also well versed in the approval procedures.

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If we put a focus on it, what regulations and standards do the products in particular have to comply with now?

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that are to be connected to the power grid, as you called it?

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So basically it's the exact same standards, so it's the well-known 60601 series standards that are also required by these N.R.T.L.s, just there with the national deviations for North America, i.e. U.S.A.

00:03:44 Speaker 3

and Canada, where they are tested.

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Very briefly back to the term you used: NRTL.

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Can you say one more sentence about who that is?

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Exactly, these are these Nationally Recognized Testing Laboratories.

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These are the testing laboratories that are accredited by the, again a longer name, this Occupational Safety and Health Administration.

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And there are really big names like UL, CSA, Intertech, ETL and then a small handful of somewhat smaller laboratories.

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but the big two best known are certainly U.L.

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and C.S.A.

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O.K., so we've already scratched a bit about the regulatory framework.

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Perhaps a term that we have again and again, the term C.B.

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Reports.

00:04:33 Speaker 2

Maybe if you can give us a short background or tell us what other evidence we ultimately need.

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So the C.B.

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Reports, that's the procedure of I.E.C.E.E.

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so in the test track of the IEC, where the goal is that not only the national country accredits the test laboratory, but also that the IEC accredits the test laboratory in order to have the same standard in testing worldwide.

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Asian countries in particular, but also often South American countries, prefer laboratories that support the CB procedure or test a CB procedure.

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Because, if I understand you correctly, once you have gone through this, you can then submit these tests again in Asian countries.

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Exactly, especially the Asian countries that say, I want a C.B.

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Certificate, otherwise I don't trust the test report that you present to me as a manufacturer.

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Are there any other proofs that are needed for the approval of the products apart from such a C.B.

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Report.

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If we now turn back to North America, plug it into the socket for it, so that's N.

00:05:50 Speaker 3

R.

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T.

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L.

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Mark, there is a so-called descriptive report.

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This is actually very similar to the content of the 60601 series, but specifically the requirements, which market can I put on it, what does the market look like, is it only U.

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S.

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A. Canada only or both countries

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and also has all the restrictions.

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Can I only use it up to an altitude of 4000 meters?

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Can I only use it together with a special power supply?

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All these additional restrictions, which apply in North America, are then described in this Descriptive Report.

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Do I understand correctly that you ultimately have 2 reports?

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Once the C.B.

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Report, with which you can then go to all countries, and the Descriptive Report, which is then specially intended for North America.

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That's exactly how it is.

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Wow, OK, that means now we have, we were at the end result, which is these reports.

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What does the laboratory have to do now in order to be allowed to fill out these reports, to be allowed to issue these certificates?

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The laboratory, so if we now call C.S.A.

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as an example, must prove that, on the one hand, it is vis-à-vis C.B.

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proceedings of the I.E.C.E., but also vis-à-vis this OSHA, i.e. this

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Safety and Health Administration that they have this ability to perform the exam.

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They have to prove that they have the know-how, that they have the equipment, that they have the appropriate rooms.

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What then always fits this bandwidth, what do we put into the socket in the USA?

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This starts with the blender in the kitchen, continues in the living room to the

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Video or television or then in the hospital to the ventilator and cover the whole bandwidth, I think to myself, is already a challenge for these laboratories.

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Mhm, what can they do now to make it particularly elegant?

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So, if I understand you correctly, they have to meet requirements themselves, of course.

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I think now probably also certain ISO standards, such as a 17025

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What else should they take into account?

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There may also be a bit of a question behind it: What should you pay attention to when choosing such a laboratory?

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Well, that's basically 5:25 p.m. for sure.

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The main topic here again regarding.

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the full traceability of the Q qualification.

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Q.

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system, i.e. quality management system.

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But now especially in the C.

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B.

00:08:26 Speaker 3

The I.

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C.

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E.

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E.

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created many additional regulations, the so-called O.

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D.

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or Operational Documents, where more is described than in the 17025

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which then also applies to a microbiological laboratory and there the O.

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D.

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then by I.

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C.

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E.

00:08:53 Speaker 3

E.

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further regulations for calibration, for verification of power sources and so on, all of which must also be complied with.

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So those were very formal things, so I understood you to be so, when you choose a laboratory, of course make sure that they have the appropriate accreditation and the appropriate

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yes, I am also allowed to exhibit reports, which you have already talked about earlier.

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So once this C.

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B.

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Report that you were talking about and then also on the other side this Descriptive Report.

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Is there anything else from the experience, things where you would say, 8 times on it, when you choose your laboratory, I think above all, if you then have special equipment, the question is always the question, can I now, when we go back into our development track, this

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Ventilators, I need a lung simulator, I need devices to measure these breaths, the individual breath, let's put it this way.

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And of course, not every laboratory has that, if it is of course something very simple, then it is very common, but as soon as it goes into a special area, it may be difficult to be able to keep the appropriate equipment available.

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Yes, I think that can be queried quite well in advance.

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Yes, do you have the necessary equipment for this special medical device?

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I think I can probably see more out how we would be Deep at which point.

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In the end, yes, sorry, although of course there is also the possibility of witness test proceedings.

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Help us briefly explain this new term, what is behind it?

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So, witness, that actually means witnessing and

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Side, i.e. the I.E.C.E.E., but also the N.R.T.L.s know this procedure.

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This means that if I, as a testing laboratory, have this ventilator in my area of application, but I now have the corresponding lung simulation device in the laboratory that I don‘t need, that I don‘t need to have in stock, but the manufacturer has, the test laboratory can qualify the manufacturer, i.e. the test laboratory of the manufacturer

00:11:05 Speaker 3

in the C.

00:11:06 Speaker 3

B.

00:11:06 Speaker 3

Procedure or even for the N.

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R.

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T.

00:11:08 Speaker 3

L.

00:11:08 Speaker 3

Mark tests at the manufacturer.

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O.

00:11:13 Speaker 2

K.

00:11:13 Speaker 2

and is there someone from U.

00:11:16 Speaker 2

L.

00:11:16 Speaker 2

or C.

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A.

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S.

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or another laboratory, if the manufacturer then carries out these tests on its premises, so they sit there.

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That's exactly why it's called Witness, so there are different levels, so in the I.E.C.E.E.

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there are stages 1 to 4 and

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a very simple Stage 1, where the certifier from the test laboratory comes to me at the manufacturer and tests itself with my equipment.

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And then at Stage 2 I am allowed to test myself, but the certifier watches and the higher the level goes, the more I am allowed to do myself as a laboratory or as a manufacturer.

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but always there with the proof of independence.

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So all the requirements of the 17:25 apply exactly the same.

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So as a manufacturer, I then have to show that my internal test laboratory complies with the requirements of 17:25 and that the NRTL or the CB test laboratory must also audit and check it.

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Mhm.

00:12:27 Speaker 2

So, it's not like ‚bring your own test equipment' to the lab, but it's actually the other way around.

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We bring the tester from the test laboratory into our company and I understood you that way, there are now different levels and the higher the level is, yes, you actually go through it in a way.

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Or will this testing body itself become more of an almost accrediting body that allows you to do things yourself more and more.

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Yes, I understood it that way, at level 1, the laboratory still does everything, but in your own rooms and the higher the level gets, the more you are let off the leash, at least from the immediate leash, then rather hangs on the leash of the quality management view, so to speak.

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Is that true?

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This is so accurate and the Customer Testing Facilities, such as the one at I.C.E.E.

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will then also be

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reported to the I.E.C.E.E.

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and listed there on the website.

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So I can then go as a buyer, so to speak, or as an end customer, who test the same thing or not and if so, it is also stored in the database for which standards, which parts of the standards and also in which of these stages, i.e. Stage 12, that this manufacturer is located.

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Are you with I.M.T.

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also listed at the I.E.C.

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for certain procedures.

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Exactly, so in the field of ventilators we are also there at the I.E.C.

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listed as a Customer Testing Facility for individual tests that we carry out at our premises, but above all with these lung simulators.

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So that means everyone, i.e. all manufacturers of ventilators who are still missing something like this, the

00:14:15 Speaker 2

then you can also come to you, because it doesn't say anywhere that it's only the products that you are now developing yourself, right?

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But it is basically always linked to the corresponding contract, where the device is to be certified afterwards, so it is always the corresponding framework contract, so to speak, with the NRTL or with the one for the CB certificate from the manufacturer of the device.

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Now you have just used the term C.B.

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again and thus also said, this is not the U.S.A.

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Specifically, you did, that's how you got involved.

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If we now broaden our view a bit, again the U.S.A.

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Is there this witness test procedure, if I have understood you now, will it also be recognized worldwide or is it useful to you worldwide?

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Exactly, the C.B.

00:15:10 Speaker 3

Certificates I

00:15:12 Speaker 3

within the framework or that I get created with this witness testing from the test laboratory, I can then use and use them worldwide.

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Wow, that saves a lot of work.

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Bert, I would say that you have once again given us a great overview of a world in which we don't usually move every day and in a double sense.

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We have moved out of Europe and have moved a bit out of the medical device world or out of the specific world and have

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looked at what possibilities are also available in the field of electrical safety, for example, but also other areas that include 60, 6 and 1, and explained to us what a witness testing procedure is.

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And I think that's an important finding, because it also gives us an opportunity to have to work with a greater variability of test laboratories that we don't have to rely on

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that the test laboratory already has all the test equipment for our specific product.

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Beat, I would say thank you very much for your Medical Device Insights.

00:16:17 Speaker 3

You're welcome and thank you very much for the invitation, Christian.