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Designated standards can help manufacturers demonstrate their products, services or processes comply with GB law. By following designated standards, manufacturers can claim, ‘presumption of conformity’ (which can be countered by evidence) with the corresponding essential requirements. Designated standards do not replace the essential requirements and manufacturers retain full responsibility for ensuring the applicable GB law is met. A designated standard is a standard, developed by consensus, which is recognised by government in part or in full by publishing its reference on GOV.UK in a formal notice of publication. Links are provided on this page to all pages on GOV.UK on which formal notices of publication are made available. For the GB market, and depending on the product, a designated standard can be a standard adopted by any of the recognised standardisation bodies (the British Standards Institution (BSI), European Committee for Standardisation (CEN), European Committee for Electrotechnical Standardisation (CENELEC) and European Telecommunications Standards Institute (ETSI)) or by international standardising bodies (including the International Organization for Standardization (ISO), International Electrotechnical Commission (IEC) and International Telecommunication Union (ITU)). Note: The content of the standard is the responsibility of the recognised standardisation bodies. As the UK’s National Standards Body, BSI represents the interests of UK stakeholders in the development of international and regional European (not EU) standards. We encourage UK stakeholders to shape the content of a standard at the earliest stage so that when it is considered for designation there is minimal risk it will not give full coverage of the relevant essential requirements. There are different ways you can get involved in standards development: view and comment on proposals for new standards view and comment on draft standards apply as a BSI committee member and provide input on the standards-making process Where there is alignment with relevant EU rules, European harmonised standards are the relevant standards for demonstrating compliance with EU law when placing goods on the Northern Ireland market. Find out about placing manufactured goods on the market in Northern Ireland The designation process From 1 January 2021, the GB regulatory framework enables the relevant Secretary of State to ‘designate’ standards for regulatory conformity purposes. The government ensures that the standards designated for the GB market meet the required levels of safety or energy efficiency. To promote consistency and guidance on the designation of standards, the Office for Product Safety and Standards (OPSS) leads and co-ordinates the designation process across government. BSI updates OPSS on new or revised standards that can be considered for designation. The government assesses whether the standards put forward are suitable for the purpose of providing a presumption of conformity to relevant essential requirements in GB law. This information is shared by OPSS with the relevant government departments and agencies responsible for designation decisions. Stakeholders wishing to propose a standard for designation should approach BSI in the first instance so that the relevant technical committee can assess if the standard is suitable to put forward for designation. When deciding if a standard is appropriate for designation, the responsible government department or agency will assess how far it covers the essential requirements set out in the relevant GB legislation. This assessment compares the provisions of the standard with the requirements of the regulation. It does not assess the quality of the standard nor its technical adequacy, which is the responsibility of BSI. If the government requires clarification on a specific issue about the standard’s suitability for designation, it will contact the appropriate technical committee through BSI. Government may decide to designate a standard in full; not to designate; or, to designate with restriction. Any such restrictions will be published on GOV.UK. It is important that stakeholders look at published notices for references that may be subject to restrictions in respect of essential requirements in GB law. Where a standard that is designated replaces an existing designated standard, there is a transition period during which both the new designated standard and the superseded standard give a presumption of conformity. This transition period will be made clear in the relevant published notice. Only the application of a designated standard will give a presumption of conformity to the relevant essential requirements. There may be instances where the reference to a designated standard is accompanied by an ‘Informative Note’. The government uses informative notes as guidance to identify an error in the standard (for example where an incorrect date has been used), to provide a clarification on an ambiguity, or to advise additional or alternative actions for business to consider outside of the standard. Where additional actions are advised, it is intended to support businesses in their approach in understanding and managing risks that they may identify with their products. OPSS maintains all designated standards pages on GOV.UK and carries out the administrative function of publishing references to standards following internal approval or when other departments and agencies have decided to designate. The government makes its proposals to publish references to standards publicly available for 28 days, to provide an opportunity for interested parties to object if they have reason to believe that a standard proposed for designation does not meet GB essential requirements, either fully or partly. Designated standards: new or amended notices of publication The references will be published to designate the standards on day 29, unless the proposal is withdrawn or amended before that date, or an objection to designation is received. The publication of references is postponed if an objection against a standard proposed for designation alleges that it does not adequately cover the relevant essential legal requirements. Please note: The designation process cannot change the content of a standard – this can only be done by the standards bodies. References of designated standards Designated standards are prefixed “BS”, “EN”, “EN ISO” or “EN IEC”. The “EN” prefix indicates that the standard has been adopted by a regional European standardising body. Where the designated standard specified in the notice of publication is prefixed “EN” it is acceptable to reference this version in technical documentation, or a version of the same standard with a national prefix. This is because regional European standards are adopted identically by the 34 national members of CEN and CENELEC. For example: BS EN 71-1:2014+A1:2018, DIN EN 71-1:2014+A1:2018, or simply EN 71-1:2014+A1:2018 are all equally acceptable. (‘DIN’ indicates the German Institute for Standardization.) While the essential legal requirements in GB remain the same as the equivalent EU law, the informative Annex ZA/ZZ and any references to EU law in designated standards should be read as applying to the legislation for GB in the same way, subject to any restrictions or points made in the relevant notice of publication. This will change if and when the essential requirements in GB change. We have asked BSI to ensure that any new or revised designated standards map across to the essential requirements in GB. Chemicals Conformity assessment and management systems New Legislative Framework (NLF) Construction Construction products (CPR) – list owned by MHCLG Consumers and workers protection Energy efficiency Electric and electronic engineering Healthcare engineering Measuring technology Mechanical engineering and means of transport The company I work for sells to a VERY large global client that has requested CE Declarations of Conformity for all components within our electrical enclosure. We have provided several sets of documents provided by our multi-billion dollar electrical manufacturers/suppliers only to be told their DoC's are not valid for a variety of reasons such as the harmonized standard being out dated, the signatory did not list their title, DIN vs. EN vs. IEC standards... the list goes on. Over the past 5 months, we have learned much about CE but still cannot find answers to some very basic questions and I'm hoping someone can help. 1. Are IEC standards harmonized? Manufacturer = Yes, Client = No 2. Can the Low Voltage Directive and ATEX directive both be listed on a DoC. 3. What can a $4M/year company do when a $27B/year supplier insists their DoC is correct as is but the +$100B/year client disagrees? I have more questions but will leave with these three for now. Any responses or suggestions on where to find answers and/or training would be greatly appreciated. Elsmar Forum Sponsor The company I work for sells to a VERY large global client that has requested CE Declarations of Conformity for all components within our electrical enclosure. We have provided several sets of documents provided by our multi-billion dollar electrical manufacturers/suppliers only to be told their DoC's are not valid for a variety of reasons such as the harmonized standard being out dated, the signatory did not list their title, DIN vs. EN vs. IEC standards... the list goes on. Over the past 5 months, we have learned much about CE but still cannot find answers to some very basic questions and I'm hoping someone can help. 1. Are IEC standards harmonized? Manufacturer = Yes, Client = No 2. Can the Low Voltage Directive and ATEX directive both be listed on a DoC. 3. What can a $4M/year company do when a $27B/year supplier insists their DoC is correct as is but the +$100B/year client disagrees? I have more questions but will leave with these three for now. Any responses or suggestions on where to find answers and/or training would be greatly appreciated. Hello and welcome to the Cove I come from the medical devices field. FWIW: 1. IEC standards are not harmonized per-se. Some of them may be harmonized under an EN designation. Each Directive has an associated list of harmonized standards that provide presumption of conformity, look at this page: http :// ec. europa. eu/enterprise/policies/european-standards/harmonised-standards/index_en.htm#h2-1. - OBSOLETE BROKEN 404 LINK(s) UNLINKED Nevertheless, the EC DoC may also list standards that are not harmonized. A manufacturer may be able to claim that a certain non-harmonized standard (an IEC one, if you like) is identical in its normative part to a harmonized one (EN), and the relevant NB may accept it; AFAIK its a matter of NB policy, but I may be wrong. 2. I have no specific experience with the ATEX directive. In general, if a single document meets all the applicable requirements listed in 2 different Directives, I don't see why it wouldn't be able to serve as the DoC for both. 3. That is a tough business question. I don't think the regulations and/or associated guidance could help with that. If you could somehow get the +$100B to talk directly with the $27B, it might help... Other than that it's always good to have alternative suppliers for critical components. Cheers, Ronen. Last edited by a moderator: Apr 6, 2019 What type of DoCs are you providing for components? - CE marking DoCs are for finished apparatus, not components. Regarding what standards are on a CE mark DoC - the manufacturer may list whatever they like. "Fully Applied" "Harmonised Standards" provide the manufacturer with a PRESUMPTION of conformity - no more and no less. Many Directives (inc EMC and LVD) do not require use of Harmonised Standards and others, such as R&TTE, allow use of non-Harmonised Standards where a Notified Body Opinion has been obtained. Unfortunately for you, many large companies take the view that compliance with Harmonised Standards is the ONLY acceptable method for CE marking - this view is not LEGALLY enforceable, but is entirely enforceable COMMERCIALLY. You might be buying components/items from large companies, but you are essentially a small company selling to a large one. You MIGHT have a chance of educating them, but more likely you need to give them what they ask for. I'll repeat my initial question though - why do they need DoC's for components? Ronen & Charlie, thank you so much for your input! Do you know of any resources that could substantiate what you have stated regarding the standards not being required to be Haromonised? We have sent several supplier explanations as to why they are using the standards they listed to our client and all have been rejected. After going back and forth with the suppliers most have altered their DoC to match what our client wants. (Doesn't seem like the best idea to me but...) Charlie, as to your question about why we are supplying our client with component level DoC's... their sales engineer apparently allowed his client in Egypt to add that level of detail into the contract so now, if they cannot provide the proper documentation, they are looking at not being paid or having to replace the parts that are deemed "non-compliant." As for our machine, we (as an ISO9001 company) self-declare CE on our finished machine. We conform to the EMC, LVD and Machinery directives. We have tested our machine to ensure it meets the EMC directive as required. We have provided our DoC for the machine and the substantiating test data but it is not enough. Our biggest issue is we submit documentation to our client and they come back and say "unacceptable" and we start going back and forth trying to find out what exactly what would be acceptable. We have been using the Europa web-site as a reference but still be cannot find concise answers to specific questions, i.e. are IEC standards harmonized, is a type written name AND title required for the signatory, etc. The bottom-line is we are trying to play by the rules but we don't know what the rules or who has the rule book. Again, thank you both very much for your previous assistance and any additional assistance you could offer. Hi, I'm glad you found my post useful. In my field - Medical Devices - most of these definitions are given in the directives, or in other specific EC legal documents referenced by the Directives, so it's only a matter of careful reading of not-too-many pages. I assume that would be the case with most other New Approach (leading to CE mark) directives. Well, maybe not so sure about the "not-too-many pages" part Regardless, it seems that the "rule book" is not so relevant because you have an extra-picky client which seems to be bullying you (at least by how you describe it). Perhaps it's time to consider a different approach. Sorry I can't help more than that. Ronen. Your DoC should be to: EMCD and LVD or EMCD and Machinery Directive (MSD) You don't declare to both LVD and MSD as they are applied "either/or". Given that you have a machine and assuming that its not one of those listed in Annex IV, you can self declare. Assessment for the MSD is based on an EHSR assessment against Annex I. This is typically done by applying(using and maybe testing against) some standards - these may or may not be Harmonised. You will also need to perform risk assessment as to risks that may occur suring use. The bottom-line is we are trying to play by the rules but we don't know what the rules or who has the rule book The MSD is far more complicated than EMCD and LVD and if you are having trouble with a customer it may be because you have missed some part of the assessment. You can't learn enough about doing an MSD assessment by reading the web - I strongly recommend that you get yourself some expert, 3rd party help. Where abouts are you based? Charlie, Thank you again for your input. We are located in the US and do have a 3rd party that has performed the EMC testing and we are scheduling the same party to do some additional testing and provide some additional assistance. Regardless of our testing, the client is not interested in our DoC for the whole machine they are interested primarily in the components. Our other issue is that it seems that the client's compliance group and the third party they have had to hire to keep up with their own demands don't view documents the same way. This morning the 3rd party rejected a DoC on a current project that they had previous accepted on another project that had higher standards for acceptance. It is really becoming a coin toss to see if a document is acceptable. Our biggest concern is providing the best possible product. We have designed our machine so it is very reliable and easy to operate. We have also looked to use only quality manufacturers whose product is available global so if there is an need to replace a part in the field it can be quickly source and easily replaced. ALL of the components that can be CE marked are CE marked but the supplier DoC just isn't up to par in many cases, at least according to this client. The client is looking to have us swap out one component for another purely based on a pretty piece of paper. We would prefer to keep what we have as the solution is proven, the components as well as the finished machine are reliable and safe. We are just at a point where we are banging our heads against a wall. In all reality, as I read what I just wrote, I don't think the "rule book" would help. Charlie, Thank you again for your input. We are located in the US and do have a 3rd party that has performed the EMC testing and we are scheduling the same party to do some additional testing and provide some additional assistance. Regardless of our testing, the client is not interested in our DoC for the whole machine they are interested primarily in the components. Our other issue is that it seems that the client's compliance group and the third party they have had to hire to keep up with their own demands don't view documents the same way. This morning the 3rd party rejected a DoC on a current project that they had previous accepted on another project that had higher standards for acceptance. It is really becoming a coin toss to see if a document is acceptable. Our biggest concern is providing the best possible product. 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If this client is important to you, maybe you should listen to them, and listen good. Don't be "right", be clever. If they care more about the "fancy piece of paper" than about the machine being brilliant, then this should be your key to Quality, in this case. What good is a reliable and user-friendly machine that sits in the warehouse?... And if your organisation doesn't have that kind of flexibility, or will to have it, maybe you should let this client go. My limited experience shows that when dealing with big clients, you could be "right" for the rest of your life, but until you yield they just won't buy from you. Why? Because they can. Cheers, Ronen. 1. Are IEC standards harmonized? Manufacturer = Yes, Client = No 2. Can the Low Voltage Directive and ATEX directive both be listed on a DoC. 1. First comes the IEC standard then it is adopted into an EN standard. Most of the EN standards are an copy of the IEC standard. I've read that about ~79% of the EN standards is an IEC. When you are doing an DoC you can write IEC/EN if the product fulfils both standards should be enough?. 2. Yes I think so, but if your product is going under Machinery directive you should write that instead of LVD as CharlieUK mentioned before. 1. Are IEC standards harmonized? Manufacturer = Yes, Client = No No. Only EN standards currently listed in the Official Journal of EU are "Harmonised Standards". Lists for various directives available at: (broken link removed) IEC standards are often developed in conjunction with CENELEC standards, any may be identical in content with an "EN wrapper". but only EN standards are Harmonised. You are not required to apply EN standards, but as only Harmonised Standards offer a presumption of conformity you would be advised to apply EN standards. Harmonised EN standards are also developed by other organisations, such as ETSI. 2. Can the Low Voltage Directive and ATEX directive both be listed on a DoC. Certainly. I would also expect such a product to also fall under EMC Directive, so that can (should) be listed on same DoC. Page 2 Are only EN listed? I though it look likes both are for some standards in the row Reference and title of the harmonised standard (and reference document). But that's only the referenced document? Elsmar Forum Sponsor Within various lists of Harmonised Standards there are standards listed as: EN ISO..... or EN IEC ..... or EN xxxx:year.....IEC xxxx:year - (where the "IEC" is part of the "title" and not the "standard number") BUT they are all EN..... Share — copy and redistribute the material in any medium or format for any purpose, even commercially. Adapt — remix, transform, and build upon the material for any purpose, even commercially. The licensor cannot revoke these freedoms as long as you follow the license terms. Attribution — You must give appropriate credit , provide a link to the license, and indicate if changes were made . You may do so in any reasonable manner, but not in any way that suggests the licensor endorses you or your use. ShareAlike — If you remix, transform, or build upon the material, you must distribute your contributions under the same license as the original. No additional restrictions — You may not apply legal terms or technological measures that legally restrict others from doing anything the license permits. You do not have to comply with the license for elements of the material in the public domain or where your use is permitted by an applicable exception or limitation . No warranties are given. The license may not give you all of the permissions necessary for your intended use. For example, other rights such as publicity, privacy, or moral rights may limit how you use the material. EN refers to “European norm” – EN Standards are European. IEC stands for International Electrotechnical Commission: IEC Standards are international. Standards that refer to the European implementation of an IEC Standard are designated EN IEC. In fact, most Ex European Standards began as IEC Standards, so they are technically equivalent and likely very similar. Today’s Standards for the EU market are now typically developed at the IEC level so the EN version will contain the IEC Standard within it. Annexes are included that provide any “national deviations” for the European Union. As an accredited testing service, Compliance Testing provides clients with the full testing services they need to achieve certification success. We have been providing worldwide compliance testing for FCC, IC and CE marks for over 60 years.We are able to offer services for the U.S., Canada, European Union, Australia/New Zealand, Korea, Japan and many other markets.Today’s marketplace, national and global, is demanding and tightly regulated. We understand these regulations backwards and forwards. Our accredited labs and technicians have spent decades continually training and updating our services in order to comply with the testing industry’s own rigorous accreditation regulations. You can depend on us to provide you with a complete spectrum of testing relative to your product and its certification needs.Compliance Testing works with some of the biggest names in the electronics industries as well as newcomers to the manufacturing field. As an industry leader, we take care to walk our clients through the process, ensuring that they are able to smoothly navigate the testing and certification process.Our lab is accredited by the ANSI National Accreditation Board. We’ve been featured in numerous industry publications as a leader in the field of testing and regulatory compliance, including being honored as the Top Telecom Testing Company of 2023 by Telecom Business Review.Our Services Include:Emission Testing to FCC and Industry Canada StandardsEmissions and Immunity Testing for CE MarkProduct Safety TestingCreation of Test Reports and assistance with your Declaration of Conformity needsIdentification of all appropriate Standards and directives for the Market you want to enterCustom testing and reporting requirements based on the Client’s individual requirementsP25 Interoperability TestingSubmission for worldwide conformity and interface with government regulatory agencies on your behalfRelationships: Together we are stronger. We deliver more success through shared goals and mutual supportAccountability: We hold ourselves to our word in every aspect of our businessIntegrity: We are honest, open, ethical, fair, and genuine. Our clients and employees trust us to adhere to our word.Quality: We provide services distinguished by a higher standard of excellence.Communication: Because communication is the foundation of every relationship, we strive to apply wherever possible in a safe environment. • BSMI – Chinese Taipai • IDA – SingaporeCompliance Testing, LLC’s division, FCC Certification, did an excellent job with our products. I applaud their way of getting tasks done in a timely manner with excellent quality to support it. Your company has exceeded our expectations.Chris Robinson, Globalstar Re: Electrical Class (Class I, II & III) vs. Medical Device CE marking Class I, II & Much longer answer: From IEC 60601-1 CLASS I refers to electrical equipment in which protection against electric shock does not rely on BASIC INSULATION only, but which includes an additional safety precaution in that means are provided for ACCESSIBLE PARTS of metal or internal parts of metal to be PROTECTIVELY EARTHED. CLASS II refers to electrical equipment in which protection against electric shock does not rely on BASIC INSULATION only, but in which additional safety precautions such as DOUBLE INSULATION or REINFORCED INSULATION are provided, there being no provision for protective earthing or reliance upon installation conditions. CLASS III equipment is used in some other standards (other than IEC 60601-1) to identify equipment that is powered from a safety extra-low voltage (SELV) mains supply system. MDD 93/42/EEC Devices shall be divided into Classes I, IIa, IIb and III. Classification shall be carried out in accordance with Annex IX. Examples (parts): Rule 1 All non-invasive devices are in Class I, unless one of the rules set out hereinafter applies. Rule 2 All non-invasive devices intended for channelling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class IIa. Rule 9 All active devices intended to control or monitor the performance of active therapeutic devices in Class IIb, or intended directly to influence the performance of such devices are in Class IIb. Rule 13 All devices incorporating, as an integral part, a human blood derivative are in Class III. Steve As an electronics manufacturer, achieving compliance with international standards is a key part of accessing markets and selling your device.Two of the most prominent, widely-used standards in the electronics field are IEC (International Electrotechnical Commission) and EN (European Norm) standards. These standards set minimum performance, safety and design requirements for electronic and electrical devices, ranging from radiofrequency (RF) emissions and immunity to safety, ability to withstand impacts, and many other performance criteria.Although IEC and EN standards are often very similar, there can be differences between these standards that you’ll need to know about if you’re aiming to achieve international compliance for your device.Below, we’ve dug into the key differences between IEC and EN standards (as well as their many similarities) to help you achieve compliance with the standards that matter for your product and target market.What Are IEC Standards?IEC standards are industry standards for electronic devices that are created by the International Electrotechnical Commission. Founded in 1906, the IEC is a global organization that publishes international standards for electrical, electronic and related technologies.Standards developed by the IEC are important for ensuring electronic devices have consistent, predictable performance worldwide. As such, they’re important for facilitating international trade and ensuring that electrical devices are safe and interoperable worldwide.Why IEC Standards Are Important for ManufacturersIEC standards cover a vast range of different electronic devices. For example, standards from the IEC apply to industrial technologies used in power generation and transmission, as well as consumer devices. As a manufacturer, adhering to IEC standards means that your product can be sold and used globally. Many countries and markets base their own legal standards on standards created by the IEC, meaning compliance with IEC standards brings you closer to market access.Differences Between IEC & EN StandardsThere are several key differences between IEC and EN standards, including an international versus regional focus, differences in how each type of standard is developed, and significant differences in scope.Regional FocusIEC standards are global, with a focus on international standardization. EN standards, on the other hand, are developed by the European Committee for Standardization (CEN), with their focus primarily on European countries.EN standards harmonize with European Union regulations and directives, making compliance important if you plan to sell your product within the European Economic Area.However, as EN standards are not worldwide in their scope, they’re less important if you don’t plan to market your product within Europe.Development and AdoptionIEC and EN standards are developed through a different process. IEC standards are created through a consensus of international experts. Manufacturers adopt them voluntarily, as there’s no legal requirement for IEC compliance in most countries.In contrast, EN standards are mandated by European Union legislation. Once an EN standard has been ratified, it becomes a national standard in all EU member countries, with compliance essential for market access.Within EU countries that use EN standards, the relevant EN standard overrides any conflicting standards, including IEC standards. Most EN standards began as IEC standards, meaning the standards are often technically similar in their requirements. Scope and ApplicationIn general, IEC standards have a broader scope than EN standards, covering a wider range of electrotechnical fields. EN standards, while primarily based on IEC standards, may include additional requirements to comply with specific EU regulations and safety concerns. This means that a product that’s fully compliant with IEC standards may not automatically meet EN standards, and vice versa.How to Achieve IEC/EN ComplianceUnderstand the RequirementsThe first step in achieving IEC/EN compliance is to understand the specific standards that are applicable to your device.As specialists in IEC and EN testing and compliance, our team can help you identify standards that apply to your device. Contact us online or call us at 866-540-5287 to discuss your device and how it may be affected by IEC and EN standards.Implement Compliance MeasuresOnce you’ve identified the relevant standards, you’ll need to implement compliance measures throughout your device’s design and manufacturing process.You’ll also need to conduct lab testing to verify that your device performs within the standards set out by the IEC and/or European Committee for Standardization. As an accredited testing lab, we can perform testing for your device to ensure it complies with all relevant IEC and/or EN standards needed for market access.Stay Informed and Up to DateStandards, including IEC and EN, are continually evolving to keep up with recent advances in technology. As such, you’ll need to stay informed about updates to both IEC and EN standards to ensure your device remains compliant. Regularly reviewing standards and participating in relevant industry forms can help you to stay ahead of changes and ensure your device remains compliant.Contact Us About IEC/EN Testing and ComplianceIEC and EN standards are often similar — in fact, many EN standards are developed based on their respective IEC standards. However, there are some differences between these standards that you will need to be aware of if you’re aiming to achieve compliance.As an accredited testing laboratory, our team can help you understand the standards that apply to your product and complete the relevant testing to achieve compliance.To request a free quote for your device, or ask our engineering team any question about IEC or EN compliance, contact us online or call us at 866-540-5287. Hello and good morning: Medical device identification in Europe, USA and Canada: What excatly is the identification of the Medical device, if it is a Software and sold "electronic" only (also NO CD, but online installed)??? Please discuss and help. Thank you! Elsmar Forum Sponsor I think there is no additional expectation other than the ones already established in those legislations, those are the requirements you need to comply with. However there could be some really tricky and special hazards to be addressed. Cheers! So, what do you think? On a Label I can put the manufacturer Name, Lot Number, date, and so on. Per 93/42 e.g. BUT: If a do it electronical, I do not have a Label. Only when Software starts, it Shows a Screen (or if you click on Information). Is the start Screen the labelling now or the Information window? Shall it include all the data as the CD Label does? OR: Do I simply have no labelling anymore? Do I Need all Information required on this first window popping up? Yepp, that about box is the only label in this case. Spot on! Cheers! OK, I think so too, but do you have any regulations or norm showing me this also (as an evidence for our assumption)=? There is no regulation that would say that explicitly what actually must be for software device the labelling itself. The thing is the manufacturer should address the legislative requirement, one of those is the labelling as a must and the implementation of the labelling requirement for software only thing is mostly this information box. The Technical File assessment will confirm whether or not your way is acceptable by your notified body. I wouldn't rely on just having the label on the box to implement the labeling requirements for a software product. Software may be installed on multiple sites and so the box may not be always available. Further, online updates are pretty typical now and so the version running could easily be different from the version identified on the box label. Bear in mind that "labeling" is a much broader scope than just labels (i.e., stick-on). A label is just a method to implement (some of) the labeling requirements. I don't think there are any prescriptive methods for labeling (identifying) the software but a pop-up at start-up is one way. I wouldn't recommend that as the ONLY way. Most applications (presuming there's a GUI) have an 'About' button / menu option that displays the pertinent information. Sagai is right in that your NB will tell you if what you have is adequate; however, that's a bit late in the game to find out if it's not. Good software engineering practices would enable ready identification of the software running, down to the latest 'patch' level. So think about this from a business standpoint. You will need to have your customers tell you when something is wrong and they will need to identify specific information to allow you to troubleshoot. Wouldn't it make sense to make this available through the software (most convenient for the user)? Thank you for your answers. Another question: In CE writing the intended use on the Label is NOT a must (if the intended use is not clear, well you can discuss this, if you open the Software and it s Manual.) BUT in the USA: Must the indented use be put on the Label (or about box)? The 21CFR801 defines the indented use, but is not clear, if you must write it on or not. Do you know and where can I read it? Whats about Canada? Do they require the intended use on the Label (about box)? By the way: we have Information about the Software (name, version, build number) and manufacturer in the about box already. BUT do we also Need like manufacturing date (Software is always active medical device) and intended use in the about box? Also the Manual and other Information is in the Software integrated already. Thank you again. Hi Chris, It is perhaps good to understand the standards development process in order to appreciate the relationship between the standards. Each country has a standards body (BSI in UK) which has technical National Committees (NC) that report in to the international Technical Committees (TC) of IEC and CENELEC (for IEC and EN standards). These National Committees are the 'members' of the IEC/CENELEC TC. Where a standard is produced in IEC there will be a decision on whether or not it is to also be embodied as an EN. If it is, then the CENELEC TC will not do any work on the standard (its member NCs will generally be members of both the IEC and the CENELEC TC so there is no need) and when the standard comes round to voting in IEC there will be parallel voting in CENELEC. Once a positive vote is received the IEC standard will be published and CENELEC will publish the standard a few months later as an EN, but they may add some technical annexes where it is deemed necessary due to European legislation (e.g. EU directives) which from memory are tagged on the end as Annex ZA, Annex ZB, etc. to distinguish them from any annexes the IEC may have included. In other cases CENELEC may work on a standard themselves and produce an EN standard that has no IEC equivalent. Once a standard has been published as an EN the National members of CENELEC are required, as members, to publish the standard unchanged in their own country. The only thing that can be added is a National Foreword. As an example, if there was an EN for plugs and sockets (which I think there is not because even in Europe there is no agreement) then BSI would need to publish this as a BS/EN unchanged, but could add a National Foreword saying "These plugs and sockets are not legal in the UK". Where there is no parallel voting and therefore no EN then BSI are able (if they desire) to publish the IEC standard as a BS IEC so that they can get income from selling it rather than it having to be bought from IEC. These standards are unchanged from the IEC. Therefore there is no difference between a BS IEC standard and an IEC standard. Similarly there is no difference between a BS EN and an EN standard (and if there is an IEC with the same number there is no difference with that either). So to answer your question there will not be any discrepancies between them but if an EN standard is supporting an EU Directive it is probably better to use the EN version due to the European Annexes (either the pure EN or the BS EN). If there is a pure BS (i.e. not BS IEC or BS EN) then it is not likely to have an international parent and may have requirements that are not reflected in any international standards. I hope this helps. Alasdair Product safety compliance is essential for all electronics companies. Non-compliance to all the NRTL and CE/Low voltage/General product safety safety markers set by the government can get you fined, or your business loss of revenue. At Compliance Testing, our goal is to help companies achieve required testing for all the requirements manufactures need, so they can proceed with marketing and other important activities. We offer worldwide compliance testing and have working relationships with NTRLs and NTRL labs to help you obtain the necessary marks and certifications.Low Voltage Directive – Compliance Testing, provides robust safety testing you can use to prove that your products are safe and compliant with the Low Voltage Directive.Machinery Directive – We can perform all tests and evaluations provided in the Machinery Directive. Compliance Testing, will finish the testing in our labs or your facility.General Product Service Directive – Compliance Testing, will provide the testing services required under the General Safety Directive to ensure your products meet the set standards.UL Standard Testing – We will help you obtain necessary NTRL marks and stamps in line with the UL Standards. This compliance certificate is required of all companies selling products in the United States.CSA Testing – This is the UL equivalent in Canada. Essentially, if you sell products in Canada, you must obtain NTRL certification marks following the applicable standards CSA outlines.Field Evaluation – Compliance Testing, can provide In-situ testing services for the CE mark. We will test, evaluate and label your products wherever you are to help you comply with all mandatory product safety standards.IEC Testing – Compliance Testing, can help you test electrical products to ensure they meet the applicable IEC standards.Medical Devices – Our team will provide the necessary testing and evaluation required to meet safety standards set for medical devices.Compliance Testing, aims to help you prevent non-compliance by providing the necessary tests and evaluations as per UL, CSA and IEC/EN standards. We offer worldwide product safety testing and understand all markers required by the different governments. Our compliance testing also includes design review, which evaluates your products in the initial design and prototyping stages. This allows your company to be part of the compliance certification process from the start and we can achieve it at your facility or ours. We also offer compliance testing for hazardous locations.Compliance Testing, seeks to identify and fix non-compliance through a series of evaluations. Our goal is to provide a fast turnaround for product safety testing and certification, so you can market the product. Once all tests are done, we produce comprehensive documentation of the process, featuring photos, technical files, support documents and construction reviews, among other parts.Compliance Testing can help you test information technology equipment (ITE), test and measurement equipment, scientific and industrial equipment. Other products include lighting equipment, audio/video equipment, medical devices, household appliances, electric tools, electrical laboratory equipment and electrical control equipment.Are you looking for a reliable partner to help you meet compliance requirements for all your products? Compliance Testing, LLC offers premium product safety testing and certifications. We can help you obtain all the necessary stamps for your products and have a global reach, offering companies NRTL and CE/Low voltage/General product safety compliance testing. Contact us today to find out more about product safety certification and testing. We have professional meeting/training space available daily or hourly for your next event. We are conveniently located in Mesa near Route 60 and Mesa Drive. Call us for a tour of our meeting space.Our 1700sf main meeting room can accommodate up to 100 people comfortably seated at training tables or banquet tables. There is also plenty of parking for your group.Items available for rent include a professional PA system, podium, HD overhead projector & screen. We offer WIFI throughout the building for internet access so your group can keep updated with communications while away from the office. We can assist with any food arrangements and staff required to support your event. Call us at 866.311.3268 to tour our lab and meeting space or to book your reservation.Training Center Clients“Many thanks for your wonderful hospitality today. I think everyone was pleased with the workshop as your arrangements were incredible. From the badges/sign in sheets, meeting room set up, A/V, lunch buffet, photography to demo support, everything was expertly coordinated and very professional. Your facility was also spotless from top to bottom. Compliance Testing set a very high bar for an IEEE EMC chapter meeting! We appreciate your efforts as well as those of Steve and your staff that contributed to a successful workshop.”-Janet O’Neil, ETS Lindgren The Federal Communications Commission requires all digital devices sold in the United States to meet the Unintentional Radiator requirements of 47CFR Part 15B. Part 15B is not a new requirement; however it is often one of the most over-looked requirements exposing the “responsible party” to FCC enforcement and potential fines.“Unintentional Radiation” is radio frequency noise generated by a device that is not used for telecommunications. This noise could potentially interfere and impact the operation of other devices, and therefore requires testing of the unintentional emissions.FCC 15B conformity is demonstrated either by a self-declaration process or a Certification. Although a Grant can be issued for a Part 15B unintentional radiator, most Applicants opt for the Suppliers Declaration of Conformity (SDoC). There is no certificate or document received by the Applicant once the testing in completed. Devices, such as radio receivers, which previously fell into the Verification procedure, can now be authorized under the SDoC. While this is a self-approval process, the Rules currently specify that the SDoC testing must still be performed by a lab that has its test site registered with the FCC. It is not necessary to perform the testing at an FCC-recognized accredited testing laboratory; however, an accredited testing laboratory may be used and is recommended by CTLOne special requirement introduced with the creation of the SDoC procedure is the creation of a ‘Responsible Party’. This may be a manufacturer, an assembler (if the equipment is assembled from individual component parts), or an importer. This party is responsible for the compliance of the equipment and must maintain a United States presence. The responsible party assumes the liabilities associated with guaranteeing compliance.For complete information, kindly refer to the FCC interpretation database under KDB 896810.Common misconceptions about Verification and Declaration of Conformity (DoC) testing:My device doesn’t have a transmitter so I don’t need any testing.I’m using an unlicensed radio so I don’t need any testing.I’m using a pre-certified module, so I don’t need any testing.“Self-Declaration” means testing is optional. For electronics manufacturer, following international rules is crucial for entering global markets and selling their products successfully. Meeting these standards not only creates new opportunities but also builds trust with customers and partners, helping the company grow and compete globally. Two of the most prominent and widely adopted standards in the electronics industry are International Electrotechnical Commission (IEC) and the European Norm (EN) . These standards play a critical role in promoting consistency and standardization across various sectors, including engineering, electronics, telecommunications, and information technology. While both IEC and EN standards aim to establish common technical guidelines, they differ in several key aspects. IEC Standards: Founded in 1906, the IEC is a global organization that creates international standards for electrical, electronic, and related technologies. IEC standards cover many electronic devices, from industrial technologies used in power generation and transmission to consumer devices. For manufacturers, following IEC standards means your products can be sold and used worldwide. Many countries base their own standards on IEC standards, so complying with them helps you access global markets. EN Standards: EN standards are created by the European Committee for Standardization (CEN), which includes national standardization bodies from various European countries. The goal of EN standards is to make trade easier within the European Single Market by setting uniform requirements for safety, compatibility, and interoperability of products and services across borders. These standards are widely accepted in European Union member states. Differences between EN and IEC Standards: 1. Scope and Applicability: IEC standards are bigger and help with trade all over the world. They make sure things can work together everywhere. EN standards primarily apply to products and services traded within the European Single Market. They aim to ensure compliance with EU laws and regulations. 2. Development Process: IEC standards are created through a consensus of international experts, which involve global experts from different regions and countries, ensuring a more diverse and international perspective. EN standards are developed within the CEN framework, which involves the participation of European national standardization bodies and relevant stakeholders. The development process follows a consensus-based approach, taking into account the needs and requirements of the European market. 3. Recognition and Adoption: IEC standards are adopted by various national standardization bodies worldwide and may be implemented with or without modifications, depending on the specific requirements of each country or region. Manufacturers adopt them voluntarily, as there’s no legal requirement for IEC compliance in most countries. EN standards are mandated by European Union legislation. Once an EN standard has been ratified, it becomes a national standard in all EU member countries, with compliance essential for market access. Within EU countries that use EN standards, the relevant EN standard overrides any conflicting standards, including IEC standards. Here is a simple chart outlining the key differences between IEC and EN standards: Aspect IEC Standards EN Standards Scope Broad international reach Focused on the European Single Market Development Process Developed by international experts Developed by European Committee for Standardization (CEN) and ratified by European Union (EU) member states Legal Enforcement Voluntary adoption in most countries Transposed into national laws in EU member states Recognition Widely recognized worldwide Legally enforceable within EU member states In summary, EN and IEC standards both want things to be the same and safe, but they have some differences. EN standards are mainly for Europe, while IEC standards are used worldwide. Knowing these differences is important for businesses in Europe or trading internationally because following the right standards is key for safety, quality, and selling products.