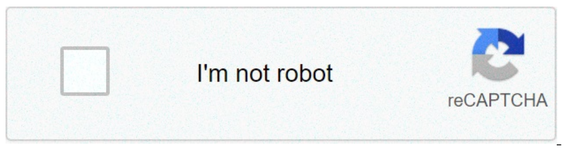

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Ce technical file example pdf

All European CE marking directives oblige the manufacturer to draw up a Technical File (or in the directives you'll also find the term 'technical documentation'). The Technical File must contain all information that is necessary to demonstrate the conformity of the product to the applicable requirements. The Technical File must be available as soon as the product is placed on the European market, whatever its geographical origin is. Typically, the Technical File must be kept for at least ten years from the last date of manufacture of the product. Some directives expressly provides for any other duration (5 years in the Medical Devices Directive and Active Implantable Medical Devices Directive and 3 years in the Directive concerning energy efficiency in household refrigerators and freezers). This is the responsibility of the manufacturer, or his authorized representative established within the Community. How to build a Technical File? What should be the content and format? The exact contents of the Technical File are not specified, although most directives give examples of documentation to be included. And as a rule, the documentation should cover the design, manufacture and operation of the product. The details included in the documentation depend on the nature of the product and on what is considered as necessary, from the technical point of view, for demonstrating the conformity of the product to the essential requirements of the relevant directive and, if the harmonized standards have been applied, to these instead by indicating the essential requirements covered by the standards. There are no requirements regarding the structure and format of the Technical File. Nowadays the files may be kept in electronic format. Please note that the documents in the Technical File must be kept up to date. So whenever there are modifications to the product, or when there are amendments in the regulations, the content of the Technical File should be updated. The rules for the exact content differ from one CE directive or regulation to another. Contact us for support in building and maintaining your Technical Files. The Technical File is one of the corner stones of the CE marking process. What are the language requirements? Several CE marking directives require that the Technical File is written in an official language of the Member State where the procedures are to be carried out, OR in which the approved certification body (so-called 'Notified Body') is established, or in a language accepted by it. Virtually all certification bodies accept documentation in English. The reason is of course that in order for the approved certification bodies to be able to carry out the conformity assessment procedures in a proper way and for the market surveillance bodies to be able to control compliance, the documentation should always be in a language understood by them. In that regard it is recommended to make the Technical File and its documentation in English or an accepted language, even if this has not been explicitly mentioned in the CE marking directives that apply to your products. TIP: If English is not the language in which your design documentation or procedures are written, we recommend you to start using it as your primary communication language for all product documentation. It saves a lot of time and money when you're making the Technical File. Who should keep the Technical File? Most CE marking directives require that a full copy of the Technical File is kept available for inspection in the territory of the European Union. If your company is located outside Europe, you will have to find a person or company to retain the Technical File. You may choose to give the Technical File to one of the European distributors. However, most manufactures do not prefer to give Technical File in the hand of its distributors, because it contains a lot of confidential design and manufacturing documentation that they do not want to disclose to the distributor. Also, they want to keep their flexibility and not lose the possibility to change distributors. If you do not have offices in the European Union, and you do not want to put your files in the hands of distributors, we can help. We offer professional Technical File retention services. We will keep the Technical File in our European Headquarters, and will represent your company as your single point of contact for regulatory and compliance inquiries. This provides you with the peace of mind that inquiries are handled professionally and with your best interests in mind. Contact us for the details and for a draft proposal. Get Help with Your Technical File Read also Manufacturers who send equipment into the EU are required to send a CE compliant product in most cases. This means that if you are making an electromechanical device, chances are that you will need to comply with at least one, maybe a few, CE marking Directives. These could include the EMC Directive 2014/30/EU, the Machinery Directive 2006/42/EC, or the Low Voltage Directive 2014/35/EU. These Directives (and the other CE marking Directives) allow the manufacturer to prove compliance on his or her own without the involvement of a regulatory authority (like OSHA through the NRTL program). The flipside of this, which is referred to as 'self-certification', is that you must retain proof that your product was in compliance when you placed it on the market in the EU. This 'proof' is compiled in the Technical File and you must be able to produce it for the authorities for ten years after you ship. This means that if you make an electric toothpick dispensing machine, and you sell many to the EU, you are required to be able to produce a Technical File for the authorities for ten years after you ship the last one to the EU. The contents of the Technical File include the Technical Reports (test reports from an accredited laboratory) bill of materials, declarations of conformity or declarations of incorporation for equipment (and sub-assemblies) incorporated into your build, general layout drawings, schematics, and anything else required to prove that your equipment complies with the applicable CE marking Directives (EU laws) that you claim to comply with. We are working with a customer who makes an electrical product and is selling this product into Europe. The distributor for this product sent our customer's technical information (i.e., his Technical File) to a 3rd party lab for review of the compliance of the equipment to applicable CE marking Directives, in this case: the EMC Directive 2011/65/EU and the RoHS Directive 2011/65/EU. The third party indicated that our customer did not comply with the Technical File requirements stated in the EMC Directive, specifically the requirements in Annex II (b) & (c): (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.; (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the apparatus; I assisted this customer by providing the below response. After I finished I thought that this could be useful information for other manufacturers. The name of the customer has been changed. John, The EMC Directive 2014/30/EU makes the requirement for a Technical File in Annex II (3.). You asked directly about 2014/30/EU, Annex II (3.) (b): (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.; ...and 2014/30/EU, Annex II (3.) (c): (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the apparatus; First – keep in mind: this is a request made by a 3rd party lab (same as if someone asked me to audit your technical file). This is not a request by market surveillance authorities: there is no legal weight to what they are asking. In regards to what they are asking for my opinion is that all you are required to supply to satisfy Annex II (3) (b) & (c) in the technical file (you aren't required to send this information to Europe unless a formal request is made) is the following: General layout drawing Electrical schematic A key if the drawing is in another language Operations and maintenance manual Supplying that information will satisfy this requirement. If you really get into this, you do not have to hand over the TF to anyone but the authorities and then only by request. I have attached the EMC Directive 2014/30/EU. Your obligations as the manufacturer are indicated in Article 7. See Article 7 (2), (3), and (9) regarding the TF. Your importer or distributor can make a case to ask you for the TF. I suggest you defend against that. The way to do it (in my opinion) is to reference this: Importers – Article 9 (8) Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form, necessary to demonstrate the conformity of apparatus in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by apparatus which they have placed on the market. Distributors – Article 10 (5) Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form, necessary to demonstrate the conformity of the apparatus. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by apparatus which they have made available on the market. Draft an agreement to hand over the TF to the authorities (or to the distributor or importer) only in a case where a written request by the authorities has been made. Other than that, all you are required to supply is the product, declaration of conformity, and the manual(s)…. That's it. I hope this helps. F2 Labs provides many CE marking services, including compilation of the Technical File so that instead of a large administrative headache at the end of your project you have everything organized on this: F2 Labs is here to help. Have a question or a comment? We can be contacted via this link. We can be reached by phone at 877-405-1580 and are here to help you. This entry was posted in ATEX Directive 2014/34/EU, CE marking, EMC Directive 2014/30/EU, General Product Safety Directive 2001/95/EC, Low Voltage Directive 2014/35/EU, Machinery Directive 2006/42/EC, Medical Devices Directive 93/42/EEC, PPE Regulation (EU) 2016/425, Pressure Equipment Directive 2014/68/EU, Product Testing, R&TTE Directive 1999/5/EC, Radio Equipment Directive 2014/53/EU, RoHS Directive 2011/65/EU and tagged ATEX 2014/34/EU, CE, CE marking, EMC 2014/30/EU, EMC Directive 2014/30/EU, EN 61326-1, Low Voltage Directive 2014/35/EU, RED 2014/53/EU, RoHS, RoHS 2011/65/EU, RoHS compliance, RoHS Directive 2011/65/EU, Technical File. Bookmark the permalink. Other Details Information on CE Technical File - documents for CE Mark certification is covered in CE Mark total documentation package, provided with free DEMO by Global Manager Group. The CE marking is a European proof of conformity and is also described as "passport" that allows manufacturers and exporters to enter products freely within the EU. Many clients are already achieved CE Mark for their products using our document kit and sample CE Mark technical file. The user can modify the templates as per their products and create CE - Mark documents for their organization based on European Union requirements. The Sample CE Technical File is helpful for Machine, Pressure, EMC, LVD, Medical device and other applicable industry products. Our sample CE technical file packages are competitively priced and effectively meet the global customer needs for product certification. The letters, "CE" -- French for "Conformity Europeans," indicate that the manufacturer has satisfied all assessment procedures specified by law for its product. Global Manager Group has globally reputed team of consultants having rich experience in preparation of sample technical file for CE certification. The user can modify the templates as per their company working system and create their own CE technical file for their product much faster and total documents are in word and easily editable. After successfully purchase of our document kit - sample CE technical file, we will provide username and password for the online delivery of our products by download from our FTP server within 12 to 24 hours. The medical device technical file is a must-have document for devices to be sold in the EU marketplace. The file contains detailed information about your medical device, its design, intended use claims, composition, and clinical evaluations. It's essentially an "everything you must know" document for a device. If you're going for a CE Mark, then you need to understand what is required of the technical file. Here's how to structure yours to successfully enter the EU: FREE CHECKLIST: Make sure you're structuring your technical documentation correctly with this helpful checklist that you can download for free by clicking here. Technical file overview The technical file has been around for a long time. A good way to think of it is that it's analogous to a 510(k) or a regulatory submission to FDA, except with a European twist, if you will. A technical file comprises a collection of evidence used in a regulatory submission to demonstrate that a product is safe and effective and that you've met the requirements for the CE Mark. One thing to make clear is that the technical file is not exactly the same as a design dossier, which can be seen as slightly more in-depth or advanced than a technical file. In the EU, the design dossier is used for the higher risk medical devices. It's very much like how a PMA is used for Class III product submissions to FDA. When is a technical file required? Basically, all types of devices entering the EU marketplace will require a technical file. What throws some manufacturers off is that some products classified as lower-risk will have a self-declaration, which does not require the permission of a Notified Body to review a technical file. Self-declaration means that your company declares your device has met the required standard. It sounds simple on the face of it, but it does mean that you are also responsible for defining the legal framework applicable to your device and identifying which assessments are necessary (tasks that a third party would otherwise undertake). No matter what classification your device is or which pathway you are taking, a technical file is necessary. You can expect that if you are going through a Notified Body, they will definitely review your file. The EU MDR states that medical device manufacturers must: Prepare technical documentation before placing a product on the market. Ensure technical documentation is made available to the market surveillance authorities (should they request to see it) as soon as the product is placed on the market. Keep records of technical documentation for 10 years from the date the product is placed on the market (unless explicitly specified otherwise). What is the structure of technical documentation? A strong structure for your technical documentation helps any reviewers to clearly see and understand your contents. The structure can help you to maintain traceability and highlight any associated risks. At a minimum, technical documentation should have: A device description and specification section. This should also have your unique device identification (UDI) number. Labeling and instructions for use. (Note: You will need a translation for the local language of the EU country you plan to enter). Detailed information on design and manufacturing. (It is recommended that you make use of flow charts to clearly show processes and relationships). You need to show the manufacturing process, suppliers, and materials used. Detailed risk management information in compliance with ISO 14971. General Safety and Performance Requirements (GSPR), formerly known as essential requirements. It identifies all the things you must do for your device type. From a design control perspective, the contents of your traceability matrix will assist you with addressing the criteria of GSPR. Verification and validation information. In terms of verification and validation, the European Commission places a heavy emphasis on clinical data - not just during design and development, but post-market, too. CERs (Clinical Evaluation Reports) should provide a comprehensive overview of the device's design and composition, as well its intended applications and any relevant literature reviews. Post-market surveillance (PMS) information, including PMS plan, post-market clinical follow-up (PMCF) plan, and periodic safety update report (PSUR). You can find more information on the requirements for the various types of technical documentation in the MDR. For example: MDR — Annex II (TD) MDR — Annex III (PMS) Who reviews technical documentation? Once your technical file is complete, you'll want to run it through some internal checkpoints before submitting it for final review by a notified body. I recommend conducting your own internal audit review. This should be carried out by a cross-functional team of design and development, quality, regulatory, and even manufacturing stakeholders. You might also choose to use external consultants to help you if you don't have the internal expertise available. It can be invaluable to have someone come in who already has expertise on your specific type of project. Greenlight Guru has a worldwide network of trusted partners who have specific expertise with technical documentation. In fact, we hosted a 5-day EU MDR & IVDR virtual summit event where over 20 of these experts presented on EU device-related topics. You can access the full session replays here to learn more about these speakers and their areas of expertise. Externally, the technical file is reviewed by a notified body, who assesses the technical documentation to determine whether all requirements have been met in order for certification to be given. FREE CHECKLIST: Make sure you're structuring your technical documentation correctly with this helpful checklist that you can download for free by clicking here. A seamless solution for managing your medical device technical file There is an expectation that a technical file should be a living document that is kept within the quality management system, alongside other key artifacts, throughout the entire product lifecycle. This would be extremely difficult to do using a paper-based system that involves manually updating and maintaining stacks upon stacks of physical documents and reports. Conversely, a robust quality system that automatically manages your technical file, PMS reporting, and helps you maintain compliance is a clear winner. Greenlight Guru is the only QMS software that is purpose-built for the medical device industry and makes the entire technical file process seamless. Get your free demo today → Looking for a design control solution to help you bring safer medical devices to market faster with less risk? Click here to take a quick tour of Greenlight Guru's Medical Device QMS software

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