Electronics Qualification Guideline

EDM-Q-201

CE Certification

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The Electronics Design and Manufacturing Guidelines principles

The Electronics Design and Manufacturing Guidelines are designed to provide all electronic supply chain actors involved in the design, qualification, industrialization and production of electronics practical guidelines to master the multi-disciplinary hardware aspects of electronic module realization and operation in a cost-effective way. The Qualification Guidelines are intended to support the qualification of materials, substrate, components, assemblies to achieve reliable, cost-competitive electronics.
Some of the characteristics of the Qualification Guidelines are:

- The guidelines refer to the relevant industry standards that are predominantly used in the international electronics industry such as those published by organizations as IPC and JEDEC. The guidelines do not replace industrial standards but define or recommend what options in the standards to use and will fill-in gaps if necessary. They provide the basis on which a company/product/product-line or application specific approach for qualification can be defined.
- Scientific argumentation and physical models form the basis of a large part of the guidelines and of the associated tools. This allows the use of the guidelines beyond the boundary of the users' experience domain. Therefore, it provides a powerful product and process innovation aid.
- The Qualification Guidelines will not specify, recommend or exclude specific brands of materials, components, suppliers or products. They define the qualification best practice.
- The Qualification Guidelines are based on verifiable physical models, standards and empirical data.

CE Certification Guideline Scope

This guideline aims at providing a better understanding of the EU rules related to the CE marking of products. It gives information about the responsibilities of the different economic actors when putting an electronic product into the EU market. Finally, a summary of the most important directives for electronic products is given.

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1. Applicable Documents

This PBA Qualification Guideline refers as part of the guideline to the most recent versions of the following documents and standards including their amendments.

93/68/EEC	CE certification directive
2016/C 272/01	The 'Blue Guide' on the implementation of EU products rules 2016.
2014/30/EU	EU directive on the harmonisation of the laws of the Member States relating to electromagnetic compatibility.
2014/53/EU	EU directive on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC.
2014/35/EU	EU directive on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits.
2011/65/EU	EU directive on the restriction of the use of certain hazardous substances (RoHS) in electrical and electronic equipment.
2012/19/EU	EU directive on waste electrical and electronic equipment (WEEE).
EN 50581	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances. Harmonized standard.
93/42/EEC	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
EDM-Q-202	Certification of Medical Devices
EDM-P-202	Product Life Cycle Management of Medical Electronics
EDM-D-202	Design of Electronics for Medical Applications

2. Applicability of the Qualification Guideline EDM-Q-201

- The recommendations given in the guideline are intended to help the user in qualifying and obtaining approval for EU market introduction of devices and products containing electronics and requiringe CE certification.
- This guideline provides a high-level, introductory guide towards CE certification.
- Details of the requirements and the methodology can be found in the referenced EU directives, standards and CE cerification guidelines.