

Electronics Qualification Guideline

EDM-Q-201

CE Certification

Version 1.0

May 2018

Contact

Geert Willems

Phone: +32 16 288962

Mobile: +32 498 91 94 64

Geert.Willems@imec.be

IMEC

Kapeldreef 75

B3001 Heverlee

Verantwoordelijke uitgevers

Luc Van den Hove - IMEC

Copyright © imec 2018 All rights reserved.

Only an authorized person is hereby permitted to view and use this document subject to the following conditions:

1. This document may be used for informational purposes only.
2. Any copy of this document or portion thereof must include the copyright notice.
3. This information is provided "AS IS" and without warranty of any kind, express, implied, statutory, or otherwise.
4. Imec shall not be liable for any actual, direct, indirect, incidental or consequential damages arising out of the use, performance or application of this document.

Permission is not granted for resale or commercial distribution or use of the document, in whole or in part, or by itself or incorporated in another work.

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.

Acknowledgement

This document was realized in collaboration with the industrial and academic partners of imec's Center of Electronics Design & Manufacturing and Sirris.

Funding organizations

IWT and VLAIO is acknowledged for funding the VIS projects especially the VIS-traject InProVoL that have provided the scientific background for the PBA Guidelines and gained the necessary industry support.

imec contributors

Geert Willems, Ph. D.
Bart Vandeveld, Ph. D.

Contributing cEDM partners

Prime author: Prof. dr. ir. Davy Pissoort, KU Leuven – Campus Brugge

Table of Contents

The Electronics Design and Manufacturing Guidelines principles.....	2
CE Certification Guideline Scope	2
Acknowledgement.....	3
1. Applicable Documents	5
2. Applicability of the Qualification Guideline EDM-Q-201	5
3. Definitions and General Principles	6
3.1. Definitions	6
3.2. General principles of CE certification.....	6
4. Directives versus Standards	7
5. Conformity assessment procedures.....	8
6. Responsibilities of the different economic actors.....	10
7. Overview of most relevant electronics related directives	10
7.1. 2014/30/EU – Electro-Magnetic Compatibility.....	10
7.2. 2014/53/EU – Radio Equipment	11
7.3. 2014/35/EU – Low-Voltage electrical equipment	13
7.4. 2011/65/EU – Restriction on Hazardous Substances	14
7.5. 93/42/EEC – Medical Devices	15
Revisions	15

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 requiring 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 certification guidelines.