Electronics Qualification Guideline

EDM-Q-202
Certification of Electronic Medical Devices

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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.

Qualification Guideline Scope

- This guideline supports the qualification and approval of electronic medical devices and of medical devices and their parts containing electronics.

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1. Applicable Documents

This PBA Qualification Guideline refers to the most recent version of the following documents and standards:

93/42/EEC	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. (MDD)
2007/47/EC	Amendment to 93/42/EEC, 98/79/EC and 98/8/EC.
90/385/EEC	Council Directive 90/385**/**EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices. (AIMDD)
98/79/EC	Directive 98/79**/**EC of the European Parliament and of the council of 27 October 1998 on in vitro diagnostic medical devices. (IVDD)
2017/745/EU	Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 on medical devices. Amendments, corrigenda and implementing measures: https://health.ec.europa.eu/medical-devices-sector/new-regulations_en
2017/746/EU	Regulation (EU) 2017/746 of the European Parliament and the Council of 5 April 2017 on in vitro diagnostic medical devices. Amendments, corrigenda and implementing measures: https://health.ec.europa.eu/medical-devices-sector/new-regulations_en.
93/68/EEC	CE certification directive
2011/65/EU	EU directive on the restriction of the use of certain hazardous substances (RoHS) in electrical and electronic equipment.
21 U.S.C.	Title 21 of the United States Code: Federal Food Drug & Cosmetic Act (FD&C).
21 CFR Ch. I	Title 21 of the Code of Federal Regulations, Chapter I: Food and Drug Administration. (US)
21 CFR part 820	U.S. Food and Drug Administration, Quality System Regulation, Part 820
ISO 13485	Medical Devices Quality Management Systems. (QMS)
ISO 14971	Medical Devices – Application of risk management to medical devices
IEC 60601	Medical Electrical Equipment basic safety and essential performance series. Identical to EN 60601 (EU) en CSA 60601 (Can). Consensus standard per FDA.
EN 60601	Medical Electrical Equipment basic safety and essential performance series. Harmonized standard.
IEC 62304	Medical Device Software – Software Life Cycle Processes. Identical to EN 62304. Consensus standard per FDA.
EN 62304:2006	Medical Device Software – Software Life Cycle Processes. Harmonized standard.
EN 50581	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances. Harmonized standard.
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-202

- The recommendations given in the guideline are intended to help the user in qualifying and obtaining approval for market introduction of electronics for medical applications.
- This guideline provides a high-level, introductory guide towards medical device certification per EU-CE or US-FDA regulations.
- Details of the requirements and the methodology can be found in the applicable EU and US regulations and standards.
- EDM-P-202 on Product Life Cycle Management of Medical Electronics provides essential information for the application of this guideline and shall be used in conjunction with this guideline.

3. Definitions

See section 3 of EDM-P-202.

4. EU Market – CE certification

4.1. Conformity assessment

4.1.1. The conformity assessment procedures depend on the Medical Device classification. Per 2017/745, Article 51, Devices shall be divided into four classes I, IIa, IIb and III, ranging from low risk to high risk, taking into account the intended purpose of the devices and their inherent risk. The classification shall be done per Classification Rules set out in Annex VIII of Regulation 2017/745.

Class I devices include:

- All non-invasive devices except
  - Devices intended for channelling or storing blood, body liquids, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body. (Rule 2)
  - Devices intended for modifying the biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids for implantation or administration into the body. (Rule 3)
  - Devices which come into contact with injured skin or mucous membrane except if they are intended as a mechanical barrier, for compression or for absorption of exudates. (Rule 4)
- Invasive devices intended for transient use (less than 60 min). (Rule 5)
- Reusable surgical instruments. (Rule 6)
- All active devices except (Rule 13):
  - Therapeutic devices intended to administer or exchange energy (Rule 9)
  - Diagnosis and monitoring devices except devices intended to illuminate the patient's body in the visible spectrum. (Rule 10)
  - Devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body. (Rule 12)
- Software except that used to take decisions with diagnosis or therapeutic purposes. (Rule 11)

All other medical devices are to be identified to belong to class IIa, IIb, or III, per Annex VIII.

4.1.2. Per 2017/745 Article 52, prior to placing a device on the market, manufacturers shall undertake an assessment of the conformity of that device, in accordance with the applicable conformity assessment procedures set out in Annexes IX to XI.

- For **all classes** of medical devices an audited Quality Management system shall be established per 2017/745 Annex IX, section 2. Per Annex IX, 2.3, the notified