
The European Union's EMC Directive 2014/30/EU

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EU Directives Overview

Historical perspective

- The “Old Approach”
 - Detailed guidance with all necessary technical and administrative requirements
 - Driven by lack of confidence in economic operators
- The New Approach
 - Developed in 1985
 - Restricts content of legislation to “essential requirements”
 - Technical details are governed by European harmonized standards
- The New Legislative Framework
 - Adopted in 2008
 - Added elements for effective conformity assessment, accreditation and market surveillance including the control of products from outside the Union.

EU Directives Overview

The New Legislative Framework

- Key components
 - Takes account of the existence of all the economic operators in the supply chain –manufacturers, authorized representatives, distributors and importers – and of their respective roles in relation to the product
 - Recognizes the different facets of the responsibilities of the various national authorities
 - Changed the emphasis of EU legislation in relation to market access from the notion of “placing on the market” to a focus on the first “making available” of a product on the EU market.
 - placed on the market = when it is made available for the first time on the Union market.
 - made available on the market = when supplied for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge
 - Introduced a comprehensive policy on market surveillance to place equal emphasis on both setting product requirements and enforcement aspects

EU Directives Overview

Other interesting components

- Intended Use/Misuse (pg 20 of the 2014 Blue Guide)
 - Market surveillance authorities are required to check the conformity of a product:
 - in accordance with its intended purpose (as defined by the manufacturer) and
 - under the conditions of use which can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behavior
 - Manufacturers must consider the conditions of use which can be reasonably foreseen prior to placing a product on the market
 - Manufacturers are not obliged to expect that users will not take into consideration the lawful conditions of use of his product



The new EMC Directive

Red text indicates new items in the 2014 version of the EMC Directive.

Directive 2014/30/EU of 26 February 2014

- Published in the Official Journal of the EU on 29 March 2014.



- Came into effect on 20 April 2014
- Repeals and replaces 2004/108/EC on 20 April 2016
- Covers products placed on the market as of 20 April 2016
 - EMCD 2004/108/EC can be used until that date
- Applies to all forms of supply
- Not applicable to custom built evaluation kits destined for professionals to be used solely at R&D facilities for such purposes

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General provisions (Chapter 1)

- Scope
 - Not applicable for aeronautical, radio, or benign apparatus.
 - Not applicable to custom eval kits for professional R&D use only
- Definitions
 - **Manufacturers**
 - any natural or legal person who manufactures apparatus or has apparatus designed or manufactured, and markets that apparatus under his name or trade mark;
 - **Authorized representatives**
 - any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;
 - **Distributors**
 - any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes apparatus available on the market;
 - **Importers**
 - any natural or legal person established within the Union who places apparatus from a third country on the Union market;

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Obligations & responsibilities of economic operators (Chapter 2)

- Manufacturers
 - Design and manufacture the apparatus in accordance with the essential requirements
 - Draw up the required technical documentation (see Annex II or III)
 - Perform the conformity assessment procedure
 - Internal production control (Annex II)
 - Type examination (Annex III)
 - Keep the technical documentation for 10 years
 - Ensure the apparatus remains compliant over its life cycle
 - Properly label the apparatus with unique identification and manufacturer details
 - Provide instructions to the user that are clear and intelligible
 - Provide all technical documentation to a competent national authority when requested and cooperate with any actions mandated.

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Obligations & responsibilities of economic operators (Chapter 2)

- Authorized representatives
 - Appointed by the manufacturer
 - Performs the tasks specified in the mandate
 - Hold the DoC and technical documentation
 - Respond to requests by a competent national authority and cooperate with any actions mandated

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Obligations & responsibilities of economic operators (Chapter 2)

- Importers
 - Ensure that the manufacturer has drawn up the required technical documentation (see Annex II or III)
 - Ensure that the manufacturer has performed the appropriate conformity assessment procedure
 - Internal production control (Annex II)
 - Type examination (Annex III)
 - Ensure the apparatus remains compliant as a result of shipping and storage
 - Properly label the apparatus with importer details
 - Ensure that clear and intelligible instructions are provided to the user
 - Keep the technical documentation for 10 years
 - Take corrective measures necessary when they consider or have reason to believe that the apparatus is not in conformity with the Directive.
 - Provide all technical documentation to a competent national authority when requested and cooperate with any actions mandated.

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Obligations & responsibilities of economic operators (Chapter 2)

- Distributors
 - Verify that the apparatus bears the CD marking.
 - Verify that clear and intelligible instructions are provided to the user
 - Ensure the apparatus remains compliant as a result of shipping and storage
 - Take corrective measures necessary when they consider or have reason to believe that the apparatus is not in conformity with the Directive.
 - Provide all technical documentation to a competent national authority when requested and cooperate with any actions mandated.

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Conformity of Equipment (Chapter 3)

- Conformity assessment procedures
 - Internal production control (Annex II)
 - EU-type examination (Annex III)
- Information concerning the use of the apparatus
 - Specific precautions that must be taken when assembled, installed, maintained or used in order to ensure conformity.
 - Apparatus that does not meet the requirements for residential areas shall be accompanied by a clear indication of such restriction of use, where appropriate also on the packaging
 - Shall be included in the instructions accompanying the apparatus.
- Fixed installations
 - For general installation, apparatus must meet all requirements.
 - For a particular installation, no assessment but the fixed installation and the precautions to be taken during installation in order not to compromise the conformity of that installation shall be documented.

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Notification of Conformity Assessment Bodies (Chapter 4)

- Requirements and obligations of notifying authorities
- Requirements, obligations, applications, changes, operations, appeals and coordination of notified bodies
- Notification procedures
- Challenging the competence of notified bodies
- Appeal against decisions of notified bodies

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Market Surveillance (Chapter 5)

- Apparatus presenting a risk at the national level
 - Procedure for where a market surveillance authority has reason to believe that an apparatus presents a risk to aspects of public interest
 - Requires notification of Member States and the Commission.
 - Definition of “risk” is left open.
- Formal Non-Compliance
 - Conditions for formal non-compliance
 - CE marking not correct, missing or improper manufacturer or importer details, problems with DoC or technical documentation
 - Member States shall require the relevant economic operator to correct the non-compliance, or the Member State concerned shall take all appropriate measures to restrict or prohibit the apparatus being made available on the market or ensure that it is recalled or withdrawn from the market.

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Market Surveillance (Chapter 5)

- Penalties
 - Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements.

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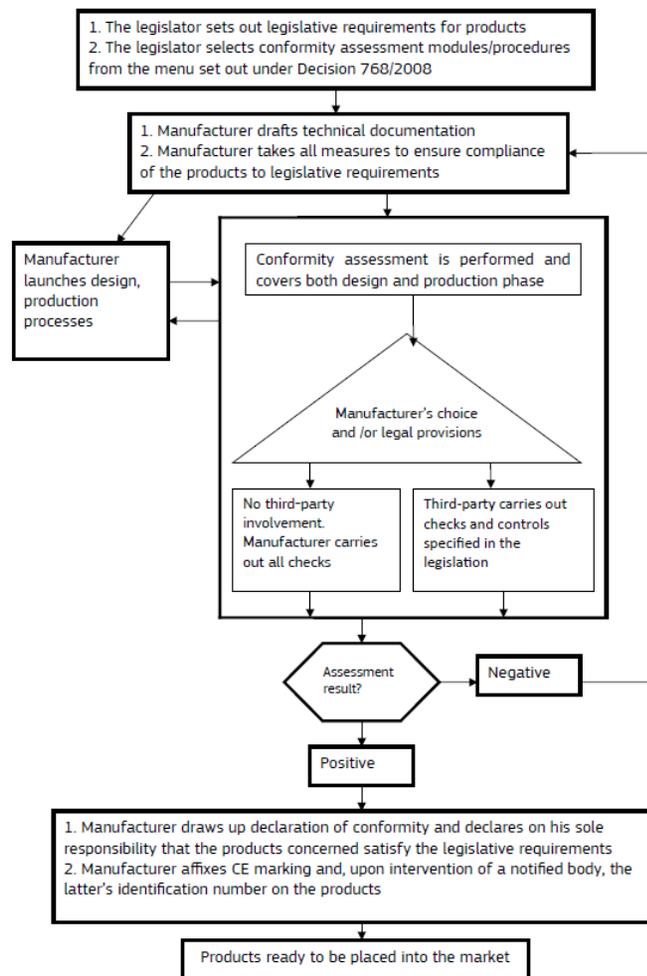
Technical (essential) requirements (Annex I)

- General requirements
 - Equipment shall be so designed and manufactured, having regard to the state of the art, as to ensure that:
 - (a) the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended;
 - (b) it has a level of immunity to the electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use.
- Specific requirements for fixed installations
 - A fixed installation shall be installed applying good engineering practices and respecting the information on the intended use of its components, with a view to meeting the general requirements.

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Conformity assessment process



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Conformity assessment procedures

- Internal production control (Annex II)
 - Assessment
 - Using harmonized standards in their entirety result in a “presumption of conformity”
 - Any other assessment
 - Technical documentation
 - General description of the apparatus
 - Conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.
 - Descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the apparatus
 - List of standards, specifications and/or methods applied to assess conformity with any partial application identified
 - Results of design calculations made, examinations carried out, etc
 - Test reports
 - Manufacturing
 - Control the process to ensure continuing conformity
 - CE marking and DoC
 - Affix the CE marking and draw up the Declaration of Conformity

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Conformity assessment procedures

- EU-type examination (Annex III)
 - Assessment
 - Performed by a notified (competent) body
 - Assesses only the technical documentation – not the actual apparatus
 - A EU-type examination certificate is issued to the manufacturer
 - Technical documentation
 - Same as for Annex II
 - Manufacturing
 - Control the process to ensure continuing conformity and notify NB of all changes
 - CE marking and DoC
 - Affix the CE marking
 - Draw up the Declaration of Conformity

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Conformity assessment procedures

- There is no requirement for the use of a notified body, regardless of approach or non-use of harmonized standards
- The manufacturer may choose to restrict application of conformity assessment procedure by internal production control (ANNEX II) to some aspects of the essential requirements, while for the other aspects of the essential requirements the procedure referred to EU type examination followed by conformity to type based on internal production control (ANNEX III).

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Declaration of Conformity (Annex IV)

- Contents
 - Apparatus model/Product (product, type, batch or serial number)
 - Name and address of the manufacturer or his authorized representative
 - Object of the declaration (identification of apparatus allowing traceability; it may include a color image of sufficient clarity where necessary for the identification of the apparatus)
 - References to the relevant harmonized standards used, including the date of the standard, **or references to the other technical specifications, including the date of the specification**, in relation to which conformity is declared
 - Where applicable, the notified body that performed the type examination and issued the certificate
- **Translated into the language or languages required by the Member State in which the apparatus is placed or made available on the market**

Where to find more

EMC

- EMC main page for the European Commission
- The new 2014 EMC Directive is available here.
- http://ec.europa.eu/enterprise/sectors/electrical/emc/index_en.htm

Harmonized EMC standards

- List of EMC standards harmonized under the EMC Directive
- http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/electromagnetic-compatibility/index_en.htm

The Blue Guide

- http://ec.europa.eu/enterprise/policies/single-market-goods/documents/internal-market-for-products/new-legislative-framework/index_en.htm

Where to find more

European Norms (standards) and OJEU

- <http://www.cenelec.eu/>

ESTI Standards

- <http://www.etsi.org/standards>