| 無線機器指令2014/53/EU | EMC指令2014/30/EU | 低電圧指令2014/35/EU | RoHS指令2011/65/EU |
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| **Article 21** **Technical documentation**1. The technical documentation shall contain all relevant data or details of the means used by the manufacturer to ensure that radio equipment complies with the essential requirements set out in Article 3. It shall, at least, contain the elements set out in Annex V.2. The technical documentation shall be drawn up before radio equipment is placed on the market and shall be continuously updated.3. The technical documentation and correspondence relating to any EU-type examination procedure shall be drawn up in an official language of the Member State in which the notified body is established or in a language acceptable to that body.4. Where the technical documentation does not comply with paragraphs 1, 2 or 3 of this Article, and in so doing fails to present sufficient relevant data or means used to ensure compliance of radio equipment with the essential requirements set out in Article 3, the market surveillance authority may ask the manufacturer or the importer to have a test performed by a body acceptable to the market surveillance authority at the expense of the manufacturer or the importer within a specified period in order to verify compliance with the essential requirements set out in Article 3. | **Article 7****Obligations of manufacturers**2. Manufacturers shall draw up the technical documentation referred to in Annex II or Annex III and carry out the relevant conformity assessment procedure referred to in Article 14 or have it carried out. | **Article 6****Obligations of manufacturers**2. Manufacturers shall draw up the technical documentation referred to in Annex III and carry out the conformity assessment procedure referred to in Annex III or have it carried out. | **Article 7****Obligations of manufacturers**Member States shall ensure that:(a) when placing EEE on the market, manufacturers ensure that it has been designed and manufactured in accordance with the requirements set out in Article 4;(b) manufacturers draw up the required technical documentation and carry out the internal production control procedure in line with **module A of Annex II to Decision No 768/2008/EC** or have it carried out;(c) where compliance of EEE with the applicable requirements has been demonstrated by the procedure referred to in point (b), manufacturers draw up an EU declaration of conformity and affix the CE marking on the finished product. Where other applicable Union legislation requires the application of a conformity assessment procedure which is at least as stringent, compliance with the requirements of Article 4(1) of this Directive may be demonstrated within the context of that procedure. A single technical documentation may be drawn up;(d) manufacturers keep the technical documentation and the EU declaration of conformity for 10 years after the EEE has been placed on the market. |
|  |  |  | **EN 50581:2012** Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances |
| **ANNEX V**  | **ANNEX II** | **ANNEX III** | **Decision No 768/2008/EC****ANNEX II****CONFORMITY ASSESSMENT PROCEDURES*****(THIS IS THE BASIC CONCEPT, TERM)*** |
| **CONTENTS OF TECHNICAL DOCUMENTATION** | **MODULE A:** **INTERNAL PRODUCTION CONTROL** | **MODULE A****Internal production control** | **Module A****Internal production control** |
|  | 1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 4 and 5 of this Annex, and ensures and declares on his sole responsibility that the apparatus concerned satisfy the requirements of this Directive that apply to it. | 1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the electrical equipment concerned satisfy the requirements of this Directive that apply to it. | 1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them. |
|  | 2. Electromagnetic compatibility assessmentThe manufacturer shall perform an electromagnetic compatibility assessment of the apparatus, on the basis of the relevant phenomena, with a view to meeting the essential requirements set out in point 1 of Annex I.The electromagnetic compatibility assessment shall take into account all normal intended operating conditions. Where the apparatus is capable of taking different configurations, the electromagnetic compatibility assessment shall confirm whether the apparatus meets the essential requirements set out in point 1 of Annex I in all the possible configurations identified by the manufacturer as representative of its intended use. |  |  |
|  | 3. Technical documentationThe manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the apparatus conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s).The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the apparatus. | 2. Technical documentationThe manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the electrical equipment’s conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s).The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the electrical equipment. | 2. Technical documentationThe manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product's conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s).The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. |
| The technical documentation shall, wherever applicable, contain at least the following elements: | The technical documentation shall, wherever applicable, contain at least the following elements: | The technical documentation shall, where applicable, contain at least the following elements: | The technical documentation shall, wherever applicable, contain at least the following elements: |
| (a) a general description of the radio equipment including: (i) photographs or illustrations showing external features, marking and internal layout; (ii) versions of software or firmware affecting compliance with essential requirements; (iii) user information and installation instructions; | (a) a general description of the apparatus; | (a) a general description of the electrical equipment; | — a general description of the product, |
| (b)conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits and other relevant similar elements; | (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.; | (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.; | — 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 radio equipment; | (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the apparatus; | (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the electrical equipment; | — descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product, |
| (d)a list of the harmonised standards  | (d) a list of the harmonised standards | (d) a list of the harmonised standards | — a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the Official Journal of the European Union, |
| applied in full or in part the references of which have been published in the Official Journal of the European Union, and,  | applied in full or in part the references of which have been published in the Official Journal of the European Union and,  | applied in full or in part the references of which have been published in the Official Journal of the European Union or international or national standards referred to in Articles 13 and 14 and,  | applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument  |
| where those harmonised standards have not been applied,  | where those harmonised standards have not been applied,  | where those harmonised standards or international or national standards have not been applied,  | where those harmonized standards have not been applied.  |
| descriptions of the solutions adopted to meet the essential requirements set out in Article 3, including a list of other relevant technical specifications applied. | descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. | descriptions of the solutions adopted to meet the safety objectives of this Directive, including a list of other relevant technical specifications applied. |  |
| In the event of partly applied harmonised standards,  | In the event of partly applied harmonised standards,  | In the event of partly applied harmonised standards or international or national standards referred to in Articles 13 and 14,  | In the event of partly applied harmonised standards,  |
| the technical documentation shall specify the parts which have been applied;  | the technical documentation shall specify the parts which have been applied; | the technical documentation shall specify the parts which have been applied; | the technical documentation shall specify the parts which have been applied, |
| (e) copy of the EU declaration of conformity; |  |  |  |
| (f) where the conformity assessment module in Annex III has been applied, copy of the EU-type examination certificate and its annexes as delivered by the notified body involved; |  |  |  |
| (g) results of design calculations made, examinations carried out, and other relevant similar elements; | (e) results of design calculations made, examinations carried out, etc.; | (e) results of design calculations made, examinations carried out, etc.; and | — results of design calculations made, examinations carried out, etc., and |
| (h) test reports;  | (f) test reports. | (f) test reports. | — test reports. |
| (i) an explanation of the compliance with the requirement of Article 10(2) and of the inclusion or not of information on the packaging in accordance with Article 10(10). |  |  |  |