

Directive 2014/53/EU of the European Parliament and of the Council of
16 April 2014 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 (Text with EEA relevance)

CHAPTER III

CONFORMITY OF RADIO EQUIPMENT

Article 16

Presumption of conformity of radio equipment

Radio equipment which is in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential requirements set out in Article 3 covered by those standards or parts thereof.

Article 17

Conformity assessment procedures

1 The manufacturer shall perform a conformity assessment of the radio equipment with a view to meeting the essential requirements set out in Article 3. The conformity assessment shall take into account all intended operating conditions and, for the essential requirement set out in point (a) of Article 3(1), the assessment shall also take into account the reasonably foreseeable conditions. Where the radio equipment is capable of taking different configurations, the conformity assessment shall confirm whether the radio equipment meets the essential requirements set out in Article 3 in all possible configurations.

2 Manufacturers shall demonstrate compliance of radio equipment with the essential requirements set out in Article 3(1) using any of the following conformity assessment procedures:

- a internal production control set out in Annex II;
- b EU-type examination that is followed by the conformity to type based on internal production control set out in Annex III;
- c conformity based on full quality assurance set out in Annex IV.

3 Where, in assessing the compliance of radio equipment with the essential requirements set out in Article 3(2) and (3), the manufacturer has applied harmonised standards the references of which have been published in the *Official Journal of the European Union*, he shall use any of the following procedures:

- a internal production control set out in Annex II;
- b EU-type examination that is followed by the conformity to type based on internal production control set out in Annex III;
- c conformity based on full quality assurance set out in Annex IV.

4 Where, in assessing the compliance of radio equipment with the essential requirements set out in Article 3(2) and (3), the manufacturer has not applied or has applied only in part

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harmonised standards the references of which have been published in the *Official Journal of the European Union*, or where such harmonised standards do not exist, radio equipment shall be submitted with regard to those essential requirements to either of the following procedures:

- a EU-type examination that is followed by the conformity to type based on internal production control set out in Annex III;
- b conformity based on full quality assurance set out in Annex IV.

Article 18

EU declaration of conformity

1 The EU declaration of conformity shall state that the fulfilment of the essential requirements set out in Article 3 has been demonstrated.

2 The EU declaration of conformity shall have the model structure set out in Annex VI, shall contain the elements set out in that Annex and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the radio equipment is placed or made available on the market.

The simplified EU declaration of conformity referred to in Article 10(9) shall contain the elements set out in Annex VII and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the radio equipment is placed or made available on the market. The full text of the EU declaration of conformity shall be available at the internet address referred to in the simplified EU declaration of conformity, in a language or languages required by the Member State in which the radio equipment is placed or made available on the market.

3 Where radio equipment is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned including their publication references.

4 By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the radio equipment with the requirements laid down in this Directive.

Article 19

General principles of the CE marking

1 The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

2 On account of the nature of radio equipment, the height of the CE marking affixed to radio equipment may be lower than 5 mm, provided that it remains visible and legible.

Article 20

Rules and conditions for affixing the CE marking and the identification number of the notified body

1 The CE marking shall be affixed visibly, legibly and indelibly to the radio equipment or to its data plate, unless that is not possible or not warranted on account of the nature of radio equipment. The CE marking shall also be affixed visibly and legibly to the packaging.

2 The CE marking shall be affixed before the radio equipment is placed on the market.

3 The CE marking shall be followed by the identification number of the notified body where the conformity assessment procedure set out in Annex IV is applied.

The identification number of the notified body shall have the same height as the CE marking.

The identification number of the notified body shall be affixed by the notified body itself or, under its instructions, by the manufacturer or his authorised representative.

4 Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

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.