
STATUTORY INSTRUMENTS

2017 No. 1206

The Radio Equipment Regulations 2017

PART 3

Conformity assessment

Presumption of conformity

40.—(1) Radio equipment which is in conformity with a harmonised standard (or part of such a standard), the reference to which has been published in the Official Journal, must be presumed to be in conformity with the essential requirements covered by that standard (or that part of that standard).

(2) The presumption in paragraph (1) is rebuttable.

Conformity assessment procedures

41.—(1) The manufacturer must perform a conformity assessment of the radio equipment, in all its possible configurations, with a view to meeting the essential requirements.

(2) The conformity assessment must take into account all intended operating conditions.

(3) In relation to the assessment of compliance with regulation 6(1)(a), the conformity assessment must also take into account all reasonably foreseeable conditions.

(4) In relation to the assessment of compliance with regulation 6(1)(a) or (b), one of the following procedures must be used—

- (a) internal production control set out in Schedule 2 (conformity assessment module A),
- (b) EU-type examination that is followed by the conformity to type based on internal production control set out in Schedule 3 (conformity assessment modules B and C),
- (c) conformity based on full quality assurance set out in Schedule 4 (conformity assessment module H).

(5) In relation to the assessment of compliance with regulation 6(2), where the manufacturer has applied harmonised standards, the references of which have been published in the Official Journal, the manufacturer must use one of the procedures in paragraph (4) for the conformity assessment.

(6) In relation to the assessment of compliance with regulation 6(2), where the manufacturer has not applied or has only partly applied harmonised standards, the references of which have been published in the Official Journal, or where harmonised standards do not exist, the manufacturer must use the procedure in either paragraph (4)(b) or paragraph (4)(c).

EU declaration of conformity

42. The EU declaration of conformity for radio equipment must—

- (a) state that the fulfilment of the essential requirements has been demonstrated in respect of that radio equipment,

- (b) contain the elements specified and have the model structure set out in Schedule 6 (EU declaration of conformity) for the relevant conformity assessment procedure followed in respect of that radio equipment.

Simplified EU declaration of conformity

43.—(1) Where only a simplified EU declaration of conformity is provided pursuant to regulation 13(3), it must contain the elements specified and have the model structure set out in Schedule 7 (simplified EU declaration of conformity).

(2) The full text of the EU declaration of conformity must be made available at the internet address referred to in the simplified EU declaration of conformity.

CE marking

44.—(1) The CE marking must 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 the radio equipment.

(2) The CE marking must be affixed visibly and legibly to the radio equipment packaging.

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

(4) When the conformity assessment procedure in Schedule 4 (conformity assessment module H) has been applied, the CE marking must be followed by the identification number of the notified body which carried out the relevant conformity assessment procedure for the radio equipment.

(5) The identification number in paragraph (4) must have the same height as the CE marking and be affixed—

- (a) by the notified body itself, or
- (b) under the instructions of the notified body, by the manufacturer or the manufacturer's authorised representative.

Technical documentation

45.—(1) The technical documentation produced by the manufacturer for the radio equipment must contain all the relevant data or details of the means used by the manufacturer to ensure that the radio equipment complies with the essential requirements.

(2) The technical documentation in paragraph (1) must—

- (a) contain, at least, the elements set out in Schedule 5 (contents of technical documentation),
- (b) be drawn up before the radio equipment is placed on the market, and
- (c) be continuously updated.

(3) The technical documentation in paragraph (1) and correspondence relating to any EU-type examination procedure must 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 the requirements in paragraphs (1), (2) or (3) and in doing so fails to present sufficient relevant data or details of the means used to ensure compliance of radio equipment with the essential requirements, the market surveillance authority may ask the manufacturer or importer to have a test performed, within a specified period, by a body acceptable to the market surveillance authority, at the expense of the manufacturer or the importer to verify conformity with the essential requirements.