

## ANNEX I

### EQUIPMENT NOT COVERED BY THIS DIRECTIVE

1. Radio equipment used by radio amateurs within the meaning of Article 1, definition 56, of the International Telecommunications Union (ITU) Radio Regulations, unless the equipment is made available on the market.

The following shall be regarded as not being made available on the market:

- (a) radio kits for assembly and use by radio amateurs;
  - (b) radio equipment modified by and for the use of radio amateurs;
  - (c) equipment constructed by individual radio amateurs for experimental and scientific purposes related to amateur radio.
2. Marine equipment falling within the scope of Council Directive 96/98/EC<sup>(1)</sup>.
  3. Airborne products, parts and appliances falling within the scope of Article 3 of Regulation (EC) No 216/2008 of the European Parliament and of the Council<sup>(2)</sup>.
  4. Custom-built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes.

## ANNEX II

### CONFORMITY ASSESSMENT 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 and 4 of this Annex, and ensures and declares on his sole responsibility that the radio equipment concerned satisfies the essential requirements set out in Article 3.

2. **Technical documentation**

The manufacturer shall establish the technical documentation in accordance with Article 21.

3. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured radio equipment with the technical documentation referred to in point 2 of this Annex and with the relevant essential requirements set out in Article 3.

4. **CE marking and EU declaration of conformity**

- 4.1. The manufacturer shall affix the CE marking in accordance with Articles 19 and 20 to each item of radio equipment that satisfies the applicable requirements of this Directive.
- 4.2. The manufacturer shall draw up a written EU declaration of conformity for each radio equipment type and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the radio equipment has been placed on

the market. The EU declaration of conformity shall identify the radio equipment for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

#### 5. **Authorised representative**

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

### ANNEX III

#### CONFORMITY ASSESSMENT MODULES B AND C EU-TYPE EXAMINATION AND CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL

When reference is made to this Annex, the conformity assessment procedure shall follow Modules B (EU-type examination) and C (Conformity to type based on internal production control) of this Annex.

#### **Module EU-type examination**

##### **B**

1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of the radio equipment and verifies and attests that the technical design of the radio equipment meets the essential requirements set out in Article 3.
2. EU-type examination shall be carried out by assessment of the adequacy of the technical design of the radio equipment through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type).
3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- (b) a written declaration that the same application has not been lodged with any other notified body;
- (c) the technical documentation. The technical documentation shall make it possible to assess the radio equipment's conformity with the applicable requirements of this Directive 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 radio equipment. The technical documentation shall contain, wherever applicable, the elements set out in Annex V;

- (d) the supporting evidence for the adequacy of the technical design solution. That supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied or have not been fully applied. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.
4. The notified body shall examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the radio equipment.
5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations as provided in point 8, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.
6. Where the type meets the requirements of this Directive that apply to the radio equipment concerned, the notified body shall issue an EU-type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the aspects of the essential requirements covered by the examination, the conditions (if any) for its validity and the necessary data for identification of the assessed type. The EU-type examination certificate may have one or more annexes attached.

The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured radio equipment with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the radio equipment with the essential requirements of this Directive or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

8. Each notified body shall inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.

Each notified body shall inform the Member States of EU-type examination certificates it has issued and/or additions thereto in those cases where harmonised standards the references of which have been published in the *Official Journal of the European Union* have not been applied or not been fully applied. The Member States, the Commission and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Member States and the Commission may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer for 10 years after the radio equipment has been assessed or until the expiry of the validity of that certificate.

9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the radio equipment has been placed on the market.
10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

### **Module Conformity to type based on internal production control**

#### **C**

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares that the radio equipment concerned is in conformity with the type described in the EU-type examination certificate and satisfies the requirements of this Directive that apply to it.

#### **2. Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured radio equipment with the approved type described in the EU-type examination certificate and with the requirements of this Directive that apply to it.

#### **3. CE marking and EU declaration of conformity**

- 3.1. The manufacturer shall affix the CE marking in accordance with Articles 19 and 20 to each item of radio equipment that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.
- 3.2. The manufacturer shall draw up a written EU declaration of conformity for each radio equipment type and keep it at the disposal of the national authorities for 10 years after the radio equipment has been placed on the market. The EU declaration of conformity shall identify the radio equipment type for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

#### **4. Authorised representative**

The manufacturer's obligations set out in point 3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

## ANNEX IV

### CONFORMITY ASSESSMENT MODULE H CONFORMITY BASED ON FULL QUALITY ASSURANCE

1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the radio equipment concerned satisfies the requirements of this Directive that apply to it.

#### 2. **Manufacturing**

The manufacturer shall operate an approved quality system for design, manufacture, final radio equipment inspection and testing of the radio equipment concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

#### 3. **Quality system**

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the radio equipment concerned.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
  - (b) the technical documentation for each radio equipment type intended to be manufactured. The technical documentation shall contain, wherever applicable, the elements set out in Annex V;
  - (c) the documentation concerning the quality system; and
  - (d) a written declaration that the same application has not been lodged with any other notified body.
- 3.2. The quality system shall ensure compliance of the radio equipment with the requirements of this Directive that apply to it.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. That quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;
- (b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the radio equipment will be met;
- (c) the design control and design verification techniques, processes and systematic actions that will be used when designing radio equipment pertaining to the radio equipment type covered;

- (d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
  - (e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
  - (f) the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel, etc.;
  - (g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.
- 3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant radio equipment field and radio equipment technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1(b) to verify the manufacturer's ability to identify the applicable requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the radio equipment with those requirements.

The manufacturer or his authorised representative shall be notified of the decision.

The notification shall contain the conclusions of the audit and the reasoned assessment decision.

- 3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
- 3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

#### **4. Surveillance under the responsibility of the notified body**

- 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- 4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:
- (a) the quality system documentation;
  - (b) the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.;

- (c) the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel, etc.
- 4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.
- 4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may, if necessary, carry out radio equipment tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.
- 5. **CE marking and EU declaration of conformity**
- 5.1. The manufacturer shall affix the CE marking in accordance with Articles 19 and 20 and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each item of radio equipment that satisfies the applicable requirements set out in Article 3.
- 5.2. The manufacturer shall draw up a written EU declaration of conformity for each radio equipment type and keep it at the disposal of the national authorities for 10 years after the radio equipment has been placed on the market. The EU declaration of conformity shall identify the radio equipment type for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

- 6. The manufacturer shall, for a period ending 10 years after the radio equipment has been placed on the market, keep at the disposal of the national authorities:
  - (a) the technical documentation referred to in point 3.1;
  - (b) the documentation concerning the quality system referred to in point 3.1;
  - (c) the change referred to in point 3.5, as approved;
  - (d) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.
- 7. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

## 8. **Authorised representative**

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

## ANNEX V

## CONTENTS OF TECHNICAL DOCUMENTATION

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;
- (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits and other relevant similar elements;
- (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the radio equipment;
- (d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, and, where those harmonised 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. In the event of partly applied harmonised standards, 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;
- (h) 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).

## ANNEX VI

EU DECLARATION OF CONFORMITY (No XXX)<sup>(3)</sup>

1. Radio equipment (product, type, batch or serial number):
2. Name and address of the manufacturer or his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer.



4. Object of the declaration (identification of the radio equipment allowing traceability; it may include a colour image of sufficient clarity where necessary for the identification of the radio equipment):
5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:  
Directive 2014/53/EU  
Other Union harmonisation legislation where applicable
6. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared. References must be listed with their identification number and version and, where applicable, date of issue:
7. Where applicable, the notified body ... (name, number) ... performed ... (description of intervention) ... and issued the EU-type examination certificate: ...
8. Where applicable, description of accessories and components, including software, which allow the radio equipment to operate as intended and covered by the EU declaration of conformity:
9. Additional information:  
Signed for and on behalf of: ...  
(place and date of issue):  
(name, function) (signature):

## ANNEX VII

## SIMPLIFIED EU DECLARATION OF CONFORMITY

The simplified EU declaration of conformity referred to in Article 10(9) shall be provided as follows:

Hereby, [Name of manufacturer] declares that the radio equipment type [designation of type of radio equipment] is in compliance with Directive 2014/53/EU.

The full text of the EU declaration of conformity is available at the following internet address:

## ANNEX VIII

## CORRELATION TABLE

| <b>Directive 1999/5/EC</b>   | <b>This Directive</b>   |
|------------------------------|---|
| Article 1                    | Article 1   |
| Article 2                    | Article 2   |
| Article 3(1) and (2)         | Article 3(1) and (2)  |
| Article 3(3) and Article 15a | Article 3(3), with the exception of Article 3(3)(i), and Article 44 |

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*Status: This is the original version (as it was originally adopted).*

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|------------------------------------|--|
| Article 4(1) and Articles 13 to 15 | Articles 8 and 45                            |
| Article 4(2)                       | —  |
| Article 5(1)                       | Article 16                                   |
| Article 5(2) and (3)               | —  |
| Article 6(1)                       | Article 6                                    |
| Article 6(2)                       | —  |
| Article 6(3)                       | Article 10(8), (9) and (10)                  |
| Article 6(4)                       | —  |
| Article 7(1) and (2)               | Article 7                                    |
| Article 7(3), (4) and (5)          | —  |
| Article 8(1) and (2)               | Article 9                                    |
| Article 8(3)                       | —  |
| Article 9                          | Articles 39 to 43                            |
| Article 10                         | Article 17                                   |
| Article 11                         | Articles 22 to 38                            |
| Article 12                         | Articles 19 and 20 and Article 10(6) and (7) |
| Article 16                         | —  |
| Article 17                         | Article 47                                   |
| Article 18                         | Article 48                                   |
| Article 19                         | Article 49                                   |
| Article 20                         | Article 50                                   |
| Article 21                         | Article 51                                   |
| Article 22                         | Article 52                                   |
| Annex I                            | Annex I                                      |
| Annex II                           | Annex II                                     |
| Annex III                          | —  |
| Annex IV                           | Annex III                                    |
| Annex V                            | Annex IV                                     |
| Annex VI                           | Article 26                                   |
| Annex VII(1) to (4)                | Articles 19 and 20                           |
| Annex VII(5)                       | Article 10(10)                               |

- (1) Council Directive 96/98/EC of 20 December 1996 on marine equipment ([OJ L 46, 17.2.1997, p. 25](#)).
- (2) Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC ([OJ L 79, 19.3.2008, p. 1](#)).
- (3) It is optional for the manufacturer to assign a number to the EU declaration of conformity.