

Decision on making available on the market of radio equipment

– unofficially consolidated text containing the provisions coming into force from 8 August 2019 –

On grounds of the provisions of the Article 108 of the Constitution of Romania, republished, of Article 22 paragraph (1) of the Government Ordinance no. 111/2011 on the electronic communications, approved, with amendments and completions, by Law no. 140/2012, with the subsequent amendments and completions, as well as of Article II of the Government Ordinance no. 8/2012 amending the Government Ordinance no. 20/2010 on the establishment of some measurements for the harmonised enforcement of the European Union legislation which harmonises the rules on products marketing, approved with amendments and completions by Law no. 55/2015,

The Romanian Government adopts the present decision

Chapter I - General provisions

Article 1. – (1) The subject matter of the present decision is to lay down:

- a) the essential requirements of the radio equipment;
 - b) the conditions for placing on the market, making available on the market and/or putting into service of radio equipment;
 - c) the conditions and requirements in order to notify the conformity assessment bodies.
- (2) Radio equipment that falls within the scope of this decision is not subject to Government Decision no. 409/2016 establishing the conditions for placing on the market of low-voltage electrical equipment, except as provided in Article 3 paragraph (1) letter a).
- (3) The present decision shall not apply to:
- a) equipment provisioned in annex no. 1;
 - b) radio equipment or devices used or intended to be exclusively used for activities concerning national defense, public order and State security, including protection of the economic interests of the State, when these interests concern the State security, as well as for activities of the State in the area of criminal law.

Article 2. – (1) For the purposes of this decision, the terms and expressions below have the following meanings:

- 1) *accreditation* – within the meaning of Article 2 point 10 of the Regulation (EC) no. 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the products marketing and repealing Regulation (EEC) no. 339/93;

- 2) *radio equipment class* – means the group including certain categories of radio equipment considered similar on grounds of this decision and the radio interfaces for which this radio equipment is intended;
- 3) *radiocommunications* – means communications via radio waves;
- 4) *distributor* – means any natural or legal person in the distribution and supply chain, other than the manufacturer or the importer, who makes radio equipment available on the market;
- 5) *radio equipment* – means an electrical or electronic product that transmits and/or receives deliberately radio waves in order to perform radio communications and/or radio determination either an electrical or electronic product which shall be completed with an accessory, such as an antenna, so as to transmit and/or receive deliberately radio waves on the purpose of radio communication and/or radio determination;
- 6) *conformity assessment* – means the process which examines how the essential requirements provisioned in this decision relating to radio equipment were fulfilled;
- 7) *importer* – means any natural or legal person, established in Romania or in other state of the European Union, who places on the Romanian market or on the market of other Member State of the European Union a radio equipment from a third country;
- 8) *radio interface* – means technical specification on the regulated use of radio spectrum;
- 9) *harmful interference* – within the meaning of the definition provisioned in Article 4 paragraph (1) point 12 of the Government Ordinance no. 111/2011 on the electronic communications, approved, with amendments and completions, by Law no. 140/2012, with the subsequent amendments and completions;
- 10) *placing on the market* – means the first making available on the Romanian or other Member State of the European Union market of a radio equipment;
- 11) *Union harmonisation legislation* – in accordance with the definition provided in Article 2 point 21 of the Regulation (EC) no. 765/2008;
- 12) *EC marking* – means a marking by which the manufacturer indicates that the radio equipment is in conformity with the applicable requirements set out in European Union harmonisation legislation providing for its affixing;
- 13) *radiocommunications station operator* – means any person to put into service or use a radiocommunications station under the law;
- 14) *economic operators* - means the manufacturer, the authorised representative, the importer and the distributor;
- 15) *conformity assessment body* - means a body that performs a public service under the public power, consisting of conformity assessment activities including calibration, testing, certification and inspection;
- 16) *national accreditation body* - within the meaning of the definition provisioned in Article 2 point 11 of the Regulation (EC) no. 765/2008;
- 17) *harmful interference* – within the meaning of the definition provisioned in Article 2 paragraph (1) point 18 of the Government Decision no. 487/2016 on the electromagnetic compatibility;

- 18) *manufacturer* - means any natural or legal person who manufactures a radio equipment or for which such equipment is designed or manufactured, and sells that equipment under his name or trade mark;
 - 19) *putting into service* – means the first use of a radio equipment in the European Union by its end-user;
 - 20) *making available on the market* - means any supply of a radio equipment for distribution, consumption or use on the on the Romanian or other Member State of the European Union market in the course of a commercial activity, whether in return for payment or free of charge;
 - 21) *radio determination* – means the determination of the position, velocity and/or other characteristics of an object, or the obtaining of information relating to those parameters, by means of the propagation properties of radio waves;
 - 22) *recall* - means any measure taken to return a radio equipment that has already been made available to the end-user;
 - 23) *authorised representative* - means any natural or legal person established in Romania or in a Member State of the European Union, who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;
 - 24) *withdrawal* - means any measure taken to prevent a radio equipment in the supply and distribution chain from being made available on the market;
 - 25) *technical specification* - means a document that prescribes technical requirements to be fulfilled by radio equipment;
 - 26) *harmonised standard* – within the meaning of the definition provisioned in Article 2 point 1 letter c) of the Regulation (EU) no. 1025/2012 of the European Parliament and of the Council of 25 October 2012 on the European standardization, amending Directives 89/686/EEC and 93/15/EEC of the Council and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Decision 87/95/ EEC of the Council and Decision no. 1673/2006/EC of the European Parliament and of the Council;
 - 27) *traceability* – means identification of persons responsible for the manufacturing, import, intra-Community purchasing, placing on the market and making available on the market of radio equipment;
 - 28) *radio waves* – means electromagnetic waves with frequencies below 3000 GHz, propagated in space without an artificial guide.
 - 29) *end-user* – any person who puts into service or uses a radio equipment.
- (2) The provisions of paragraph (1) shall be completed accordingly with the provisions of Article 4 paragraph (1) of the Government Emergency Ordinance no. 111/2011, approved with amendments and completions by Law no.140/2012, with the subsequent amendments and completions, as well as those of Regulation (EC) No. 765/2008.

Article 3. – (1) Radio equipment shall be manufactured in a way that complies with the following essential requirements:

- a) the protection of health and safety of persons and of domestic animals, and the protection of property including the objectives with respect to safety requirements set out in the Government Decision no. 409/2016, but with no voltage limit applying;
 - b) an adequate level of the electromagnetic compatibility as it is set out in Government Decision no. 487/2016.
- (2) Radio equipment shall be so manufactured as to also comply with the essential requirement to use in an optimum way radio spectrum and support its efficient use in order to avoid harmful interference.
- (3) Radio equipment within certain categories or classes shall be so manufactured that it complies with the following essential requirements:
- a) radio equipment interworks with accessories, in particular with common chargers;
 - b) radio equipment interworks via networks with other radio equipment;
 - c) radio equipment can be connected to interfaces of the appropriate type throughout the European Union;
 - d) radio equipment does not harm the network or its functioning nor misuse network resources, thereby causing an unacceptable degradation of service;
 - e) radio equipment incorporates safeguard systems to ensure that the personal data and privacy of the user and of the subscriber are protected;
 - f) radio equipment supports certain features ensuring protection against fraud;
 - g) radio equipment supports certain features ensuring access to emergency services;
 - h) to have certain features that facilitated its use by persons with disabilities;
 - i) radio equipment supports certain features in order to ensure that software can be loaded into the radio equipment only where the compliance of the combination of the radio equipment and software has been demonstrated.
- (4) The categories or classes of radio equipment regarding the essential requirements provided in paragraph (3) are the subject of European Commission delegated acts and are not hereby regulated.

Article 4. – (1) Producătorii de echipamente radio și de software care permit ca echipamentele radio să fie utilizate conform destinației și care fac parte din acele categorii sau clase de echipamente radio prevăzute de către Comisia Europeană trebuie să furnizeze Autorității Naționale pentru Administrare și Reglementare în Comunicații, denumită în continuare ANCOM, și Comisiei Europene informații privind conformitatea combinațiilor de echipament radio-software prevăzute cu cerințele esențiale prevăzute la art. 3.

(2) Such information provided at paragraph (1) shall result from a conformity assessment carried out in accordance with Articles 18 and 19 and shall be given in the form of a EU statement of compliance which includes the elements set out in Annex no. 6.

(3) Depending on the specific combinations of radio equipment and software, the information provisioned at paragraph (1) shall precisely identify the radio equipment and the software which have been assessed, and it shall be continuously updated.

Article 5. – (1) As from 12 June 2018, manufacturers shall register, in the system provided by the European Commission, radio equipment types within categories of radio

equipment affected by a low level of compliance with the essential requirements set out in Art. 3.

(1¹) The categories of radio equipment targeted by the provisions of paragraph (1) are established by the European Commission through delegated acts.

(2) Registering shall be done before the radio equipment within categories provisioned at paragraph (1) are placed on the market.

(3) When registering such radio equipment types provisioned at paragraph (1), manufacturers shall provide some, or where justified, all elements of the technical documentation listed at letters a) and d) - i) of Annex no. 5.

Article 6. – (1) Radio equipment may be made available on the market by the economic operators, put into service and/or used only if it complies with the requirements of this decision and only when it is properly installed, maintained and used for its intended purpose.

(2) By exemption from the provisions of paragraph (1), the temporary display and/or demonstrations of radio equipment which does not comply with this decision are allowed at trade fairs, exhibitions and similar events, provided that a visible sign clearly indicates that such radio equipment may not be made available on the market or put into service until it has been brought into conformity with this decision.

(3) Use of radio equipment demonstrations can take place only if appropriate measures are taken, as provided by ANCOM, in order to avoid harmful interference, electromagnetic disturbances, and risks of health or safety of persons, domestic animals and the protection of property.

Article 7. – (1) Authorisation of putting into service and use of radio equipment, if it complies with the requirements of this decision, is fulfilled by ANCOM in accordance with the provisions of the Government Emergency Ordinance no. 111/2011, approved, with amendments and completions, by Law no. 140/2012, with the subsequent amendments and completions, as well as with the provisions of the Broadcasting Law no. 504/2002, with the subsequent amendments and completions.

(2) Additional to the requirements set out in Article 6 paragraph (1), ANCOM may impose requirements on the putting into service and/or use of radio equipment, requirements on use of used radio frequencies, for reasons relating to:

- a) effective and efficient use of radio spectrum;
- b) avoidance of harmful interference or electromagnetic disturbance;
- c) transgression of the benchmarks set under the law on limitation of general population exposure to electromagnetic fields.

(3) Requirements set out in paragraph (2) can be imposed without this being in contradiction with provisions of Article 6 paragraph (1) applicable to the radio equipment on making available on the market, putting into service and/or use of equipment or with usage conditions of radio frequencies established by law.

(4) In order to comply with the rules on limiting exposure of population to electromagnetic fields effects, the holder of the license, granted according to the law, has the obligation to ensure, for the entire duration of use of the radiocommunications/broadcasting stations, compliance with the essential requirement under Article 3 paragraph (1) letter a).

(5) The holder of the license, granted according to the law, has the obligation to forward, at the request of ANCOM, in the case of radiocommunications/emission stations placed within the localities and outside the buildings, the results of the non-ionizing electromagnetic radiation measurements indicating the value of the cumulative electromagnetic field in the targeted site. The measurements are performed according to the recommendations of the Electronic Communications Committee (ECC) within the European Conference of Postal and Telecommunications Administrations (CEPT).

(6) The measurements provisioned under paragraph (5) shall not be older than 24 months from the date of the request, and their submission shall meet the deadline and the proceedings established by ANCOM.

(7) ANCOM may request the information provisioned under paragraph (5) in accordance with paragraph (6) and in order to comply with the provisions of paragraph (2) letter c).

Article 8. – ANCOM notifies, in accordance with the procedure laid down in Government Decision no. 1016/2004 on measures for the organization and exchange of information on technical standards and regulations and of rules on information society services between Romania and the Member States of the European Union and the European Commission, with the subsequent amendments and completions, radio interfaces they intend to regulate, except:

- a) radio interfaces that fully comply and without any divergence the provisions of the European Commission on the harmonised use of radio spectrum adopted under Decision No. 676/2002/EC of the European Parliament and of the Council of 7 March 2002 on a regulatory framework for policy management of radio spectrum in the European Community (Decision for radio spectrum); and
- b) radio interfaces that correspond to certain radio equipment which can be put into service and used without restrictions within the European Union, in accordance with the documents adopted by the European Commission.

Article 9. – (1) The making available on the market of radio equipment which comply with the provisions of this decision cannot be prevented.

(2) In Romania are prohibited the manufacture, import, possession, advertising, placing on the market, making available on the market, putting into service and/or use of radio equipment or devices designed to cause harmful interference.

Chapter II – Obligations of economic operators

Article 10 - Manufacturers have the following obligations:

- a) to affix on the radio equipment placed on the market the registration number assigned by the European Commission for each type of radio equipment registered under Article 5;
- b) to ensure that radio equipment placed on the market were designed and manufactured in accordance with the essential requirements set out in Article 3;
- c) to ensure that the radio equipment is manufactured so that it may operate without breaching the applicable requirements on the use of radio spectrum;

- d) to establish the technical documentation provided in Article 23 and carry out the relevant conformity assessment procedure provided in Articles 18 and 19 or have it carried out;
- e) to draft EU declaration of conformity and to affix the EC mark, where it has been demonstrated the compliance of the radio equipment with the applicable requirements by the conformity assessment procedure provided in Articles 18 and 19;
- f) to keep the technical documentation and the EU declaration of conformity for 10 years after the radio equipment was placed on the market;
- g) to establish procedures that ensure continued conformity of series production with the provisions of this decision and to ensure that changes in the design or changes to radio equipment features and changes of the harmonised standards under Article 17 paragraph (1), or of other technical specifications in relation to which the conformity of radio equipment is declared are properly taken into account;
- h) to conduct, in order to protect the health and safety of end-users, whenever this is justified by the risks of radio equipment, technical tests at random on the radio equipment made available on the market, investigate and, where appropriate, to keep a register of complaints on non-compliant radio equipment and their recalls;
- i) to inform distributors about the monitoring activities referred to letter h);
- j) to ensure that on the radio equipment they place on the market is marked type, batch or serial number or any other element allowing their identification; where the size or nature of radio equipment does not allow it, to ensure that the required information is provided on the packaging or in a document accompanying the radio equipment;
- k) to indicate on radio equipment the name, trade name or registered trademark and mailing address at which they can be contacted; where the size or nature of radio equipment does not allow it, this information is provided on the packaging or in a document accompanying the radio equipment; the address specified by the manufacturer shall indicate a single contact point and the contact details have to be in Romanian;
- l) to ensure that the radio equipment is accompanied by user instructions and safety information referred to in Art. 11, written in Romanian;
- m) to ensure that each radio equipment is accompanied by a copy of the EU declaration of conformity or by the simplified EU declaration of conformity, presented in Romanian or in English language; the simplified EU declaration of conformity shall include the exact Internet address where the full text of the EU declaration of conformity is to be obtained;
- n) to mention, on radio equipment packaging and in user instructions, the restrictions concerning its putting into service, geographic areas or regions where an authorisation for radio spectrum usage is necessary, as the case may be;
- o) to take immediately any necessary corrective action to bring the radio equipment into conformity, to withdraw and/or recall it, as appropriate, if they have evidence or information that a radio equipment which they have placed on the market does not comply with the provisions of this decision;
- p) to inform immediately the market surveillance and radio equipment control authorities if the radio equipment which they have placed on the market poses a risk, giving details, in particular, on the non-compliance, on any corrective actions taken and on their outcome;

- q) to provide, upon reasoned request received from the market surveillance and control authorities and within the term set by them, in paper or electronic form, all required information and documentation necessary to demonstrate the conformity of the radio equipment with the provisions of this decision, presented in Romanian or in English language;
- r) to cooperate with market surveillance and radio equipment control authorities, upon their request, on any action taken to eliminate the risks of radio equipment which they placed on the market.

Article 11. – (1) Instructions provisioned at Article 10 letter l) shall be clear, understandable, intelligible and relevant and shall include:

- a) necessary information on the use of radio equipment for its intended purpose;
- b) a description of accessories and components, including the software, that allows radio equipment to function for its intended purpose;
- c) the frequency band(s) in which the radio equipment operates intentionally emitting radio waves and maximum radio-frequency power transmitted in the frequency band(s) in which it operates.

(2) All information provided at paragraph (1) is provided to the end-users as a user manual written in Romanian, in paper format. Information may be provided on a durable support as well, upon the end-user's consent, according to Article 2 point 30 of Government Decision no. 487/2016 on electromagnetic compatibility.

Article 12. – (1) A manufacturer may decide, by means of a written mandate, to appoint an authorised representative.

(2) The obligation laid down in Article 10 letter b) and the obligation to draw up the technical documentation provided in Article 10 letter d) are not a part of the mandate of the authorised representative.

(3) The authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following tasks:

- a) to keep the EU declaration of conformity and the technical documentation at the disposal of market surveillance and radio equipment control authorities for 10 years after the radio equipment has been placed on the market;
- b) provide, further to a reasoned request from the radio equipment market surveillance and control authorities, in paper or electronic form, all the information and documentation necessary to demonstrate the conformity of the radio equipment, presented in Romanian or in English language;
- c) to cooperate with the market surveillance and radio equipment control authorities, at their request, on any action taken to eliminate the risks posed by radio equipment covered by the authorised representative's mandate.

Article 13. – Importers have the following obligations:

- a) to ensure that the radio equipment placed on the market is compliant with the provisions of this decision;

- b) to ensure, before placing on the market of radio equipment that the appropriate conformity assessment procedure referred to in Articles 18 and 19 was fulfilled by the manufacturer and that the radio equipment is manufactured so that it can operate without breaching the applicable requirements on the use of radio spectrum established by law;
- c) to ensure that the manufacturer has drawn up the technical documentation, that the radio equipment bears the EC marking and meets the requirements provisioned in Article 21 that it is accompanied by the information and documents provided in Article 10 letters l) -n) and that the manufacturer has complied with the requirements of Articles 10 letters j) -k);
- d) not to place on the market the radio equipment in case they have evidence or information that it does not comply with the essential requirements set out in Article 3, before being brought into conformity, and, for safety reasons, to inform the manufacturer and the market surveillance and radio equipment control authorities;
- e) to indicate on the radio equipment the name, trade name or the registered trademark and the mailing address at which they can be contacted or, if this is not possible, if the size of radio equipment does not allow it, or should open the packaging to fill in the name and address on the radio equipment, on the packaging or in a document accompanying the radio equipment; the contact details shall be written in Romanian;
- f) to ensure that radio equipment accompanied by the user instructions and safety information referred to in Article 10 letter l) meets the requirements provisioned in Article 11;
- g) to ensure that as long as the radio equipment is under their responsibility, the storage or transport conditions do not jeopardize its compliance with the essential requirements set out in Article 3;
- h) to conduct, in order to protect the health and safety of end-users, whenever this is justified by the risks of radio equipment, technical tests at random on the radio equipment made available on the market, to investigate and, where appropriate, to keep a register of complaints on non-compliant radio equipment and their recalls;
- i) to inform the distributors of any monitoring activities referred to letter h);
- j) to take immediately any necessary corrective action to bring the radio equipment into conformity, to withdraw and/or recall it, as appropriate, if they have evidence or information that a radio equipment which they have placed on the market does not comply with the provisions of this decision and immediately inform the market surveillance and radio equipment control authorities if they ascertain that the radio equipment poses a risk that can affect its operation or the operation of other radio equipment or for safety reasons, giving details, in particular, on the non-compliance and on any corrective actions taken;
- k) to keep a copy of the EU declaration of conformity for 10 years after the radio equipment was placed on the market and to ensure that the technical documentation can be made available to the market surveillance and radio equipment control authorities, upon their request;
- l) to provide the market surveillance and radio equipment control authorities, upon their reasoned request and within the term set by them, in paper or electronic form, with all

information and documentation necessary to demonstrate the compliance of the radio equipment with the provisions of this decision, presented in Romanian or in English language;

- m) to cooperate with the market surveillance and radio equipment control authorities, upon their request, on any action taken to eliminate the risks of radio equipment which they have placed on the market.

Article 14. – Distributors have the following obligations:

- a) to ensure that the way in which they make available the radio equipment on the market is not likely to affect the essential requirements set out in this decision;
- b) to check, before to make available the radio equipment on the market, if they bear the EC mark and meet the requirements of Article 21, if they are accompanied by the documentation referred to in this decision, as well by user instructions and safety information referred to in Article 10 letter l), with due observance of the requirements of Article 11 as well and that the manufacturer and the importer have complied with the requirements of Article 10 letter c) letters j) -n), respectively Article 13 lit. e);
- c) not to make available the radio equipment on the market, if they have evidence or information that the radio equipment is not compliant with the essential requirements set out in Article 3 before it is brought into compliance and, for safety reasons, to inform the manufacturer or importer, and the market surveillance and radio equipment control authorities;
- d) to ensure that, as long as the radio equipment is under their responsibility, storage or transport conditions do not jeopardize its compliance with the essential requirements set out in Article 3;
- e) to ensure that the necessary corrective actions are taken to bring the radio equipment into conformity, to withdraw and/or recall it, as appropriate, if they hold indications or information that an apparatus which they made available on the market does not comply with the provisions of this decision and to immediately inform the market surveillance and radio equipment control authorities of the Member States where they made the radio equipment available on the market, if they find that the radio equipment poses a risk that may affect its operation or the operation of other equipment or for safety reasons, giving details, in particular, on the non-compliance and on any corrective actions that were taken;
- f) to provide the market surveillance and radio equipment control authorities, upon their reasoned request and within the term set by them, in paper or electronic form, all information and documentation necessary to demonstrate the compliance of the radio equipment with the provisions of this decision, presented in Romanian or in English language;
- g) to cooperate with the market surveillance and radio equipment control authorities, upon their request, on any action taken to eliminate the risks of radio equipment which they have made available on the market.

Article 15. – The importer or the distributor is considered a manufacturer under this directive and is subject to the obligations of the manufacturer according to Article 10, when a

radio equipment is placed on the market under his name or trademark or modifies a radio equipment already placed on the market in a manner which may affect its compliance with the provisions of this decision.

Article 16. – (1) Economic operators are required to provide, upon request of the market surveillance and radio equipment control authorities, the identification data for:

- a) any economic operator who supplied them with a radio equipment;
- b) any economic operator to whom they provided with radio equipment.

(2) Economic operators have the obligation to preserve and present the information referred to in paragraph (1) for 10 years after the radio equipment has been supplied to them and for 10 years after they have provided the radio equipment.

Chapter III – Conformity of radio equipment

Article 17. – (1) Radio equipment which is compliant with the provisions of the Romanian standards and/or with national standards of other member states of the European Union which adopt harmonised standards or with parts thereof references of which have been published in the Official Journal of the European Union shall be presumed to meet the essential requirements set out in Article 3, covered by those standards or parts thereof.

(2) Harmonised standards referred to in paragraph (1) are not binding, any other means to prove compliance being permitted as well.

(3) If it is considered that a harmonised standard referred to in paragraph (1) does not fully meet the essential requirements provisioned in Article 3, ANCOM notifies the European Commission in accordance with Article 11 paragraph (1) of the Regulation (EU) no. 1.025/2012 of 25 October 2012 on the European standardization, amending Directives 89/686/EEC and 93/15/EEC of the Council and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Decision 87/95/EEC of the Council and Decision no. 1.673/2006/EC of the European Parliament and of the Council.

(4) In the situation provided in paragraph (3), ANCOM will give its reasons therefor, in a substantiated manner.

Article 18. – (1) The manufacturer has the obligation to perform a conformity assessment of the radio equipment with a view to meeting the essential requirements set out in Article 3.

(2) The conformity assessment of radio equipment shall take into account all intended operating conditions.

(3) For the essential requirement set out in Article 3 paragraph (1) letter (a), the conformity assessment shall take into account the reasonably foreseeable conditions.

(4) 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.

Article 19. – (1) The manufacturer shall demonstrate the compliance of radio equipment with the essential requirements set out in Article 3 paragraph (1) using any of the following conformity assessment procedures:

- a) internal production control set out in Annex no. 2;
- b) EU-type examination, followed by the type conformity based on internal production control, set out in Annex no. 3;
- c) conformity based on full quality assurance set out in Annex no. 4.

(2) Where, in the compliance assessment process of radio equipment with the essential requirements set out in Article 3 paragraphs (2) and (3), the manufacturer 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 no. 2;
- b) EU-type examination, followed by the type conformity based on internal production control set out in Annex no. 3;
- c) conformity based on full quality assurance set out in Annex no. 4.

(3) Where, in the compliance assessment process of radio equipment with the essential requirements set out in Article 3 paragraphs (2) and (3), the manufacturer did not apply or applied only in part harmonised standards the references of which were published in the Official Journal of the European Union, or where such harmonised standards do not exist, one of the following procedures is applied for the assessment of radio equipment:

- a) EU-type examination that is followed by the conformity to type based on internal production control set out in Annex 3;
- b) conformity based on full quality assurance set out in Annex 4.

Article 20. – (1) The EU declaration of conformity written in accordance with Article 10 letter e), shall state that the fulfilment of the essential requirements set out in Article 3 has been demonstrated.

(2) The EU declaration of conformity is drawn up and shall contain all the elements set out in Annex no. 6. The EU declaration of conformity shall be continuously updated.

(3) The EU declaration of conformity is presented in Romanian or in English language.

(4) The simplified EU declaration of conformity provisioned in Article 10 letter m) shall contain all the elements set out in Annex no. 7 and shall be continuously updated.

(5) The simplified EU declaration of conformity for radio equipment placed on the market or made available on the market in Romania shall be drawn up in Romanian.

(6) Where radio equipment is subject to more than one normative acts of the European Union requiring an EU declaration of conformity, the manufacturer shall draw up a single EU declaration of conformity. This declaration shall contain mentions on the identification of all the concerned acts, including their publication references.

(7) By drawing up the EU declaration of conformity, the manufacturer shall take responsibility for the compliance of the radio equipment with the requirements laid down in this decision.

Article 21. – (1) The provisions set out in Article 30 of Regulation (EC) No 765/2008 are applicable to the EC marking.

- (2) On account of the nature of radio equipment, the height of the EC marking affixed to radio equipment may be lower than 5 mm, provided that it remains visible and legible.
- (3) The EC marking shall be affixed before the radio equipment is placed on the market.
- (4) The EC marking shall be affixed visibly, legibly and indelibly to the radio equipment or to its data plate, unless that is not possible or justified on account of the nature of radio equipment. The EC marking shall also be affixed visibly and legibly to the packaging.
- (5) The EC marking shall be accompanied by the identification number of the notified body where the conformity assessment procedure set out in Annex no. 4 is applied. The identification number of the notified body shall have the same height as the EC marking.
- (6) In the situation provided in paragraph (5), 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.

Article 22. – If the staff of the market surveillance and radio equipment control authorities finds that the EC marking was not properly applied, the manufacturer or his authorised representative established in Romania work to bring radio equipment in accordance with the EC marking.

Article 23. – (1) The technical documentation shall contain all relevant data and details concerning the means used by the manufacturer to ensure that radio equipment complies with the essential requirements set out in Article 3. It shall contain the elements set out in Annex no. 5, at least.

- (2) The technical documentation shall be drawn up before the 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, drawn up by a body notified by the Ministry of Communications and Information Society, hereinafter referred to as MCSI, is written in Romanian.
- (4) Where the technical documentation does not comply with the provisions of paragraphs (1)-(3), and in so doing is not able to offer sufficient relevant data or means used to ensure compliance of radio equipment with the essential requirements set out in Article 3, ANCOM or National Authority for Consumer Protection, hereinafter referred to as ANPC, as the case may be, may ask the manufacturer or the importer to have technical tests performed by a body accepted by the relevant market surveillance and radio equipment control authority.
- (5) Technical tests provisioned in accordance with paragraph (4) are performed in order to verify the compliance with the essential requirements set out in Article 3, at the expense of the manufacturer or the importer.

CHAPTER IV – Conformity assessment bodies

Article 24. – (1) MCSI, in its quality of notification of conformity authority shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with the provisions of Article 28.

(2) MCSI shall notify the European Commission and the responsible authorities in the other Member States of the European Union and European Economic Area on the bodies that are authorised to perform conformity assessment activities.

(3) MCSI shall inform the European Commission on the assessment and notification procedure of the conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

Article 25. – (1) MCSI, in order to fulfill its role of notification authority has the following obligations:

- a) to fulfil the requirements set out in Art. R¹⁵ paragraph (1) in Annex I of Decision 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Decision 93/465/EEC of the Council;
- b) to safeguard the objectivity and impartiality of its activities;
- c) to ensure that each decision on the notification of the conformity assessment body is taken on the suggestions or results of the analysis of competent persons, having the professional training or necessary qualifications required in the field of electronic communications, electronics or their equivalents, different from those who carried out the assessment;
- d) to fulfil the requirements set out in Article R¹⁵ paragraph (4) in Annex I of Decision 768/2008/EC;
- e) to fulfil the requirements set out in Article R¹⁵ paragraph (5) in Annex I of Decision 768/2008/EC;
- f) to have a competent personnel at its disposal having the professional training or necessary qualifications required to check the fulfilment of the requirements set out in Article 26, and a sufficient number of persons at its disposal for the proper performance of its tasks.

(2) The provisions of paragraph (1) letter a) shall apply in compliance with the provisions of Law no. 161/2003 on some measures to ensure transparency in the exercise of public dignities, public functions and in business environment, in prevention and punishment of corruption, with the subsequent amendments and completions.

Article 26. – (1) For the purposes of notification to the European Commission and to the competent authorities in the other Member States of the European Union and European Economic Area, the conformity assessment body shall meet the following requirements:

- a) to be established according to the law and have legal personality;
- b) to be a third-party body, independent of the organization or the radio equipment which it assesses; a body belonging to a business association or to a professional federation representing undertakings involved in the design, manufacture, provision, assembly, usage or maintenance of radio equipment which it assesses may be considered a conformity assessment body, with the condition to demonstrate its independence and that it has no interest of patrimonial nature which could influence the objectivity of carrying out its attributions according to the normative acts in

force, as it is provisioned in Article R¹⁷ paragraph (3) in Annex I to the Decision 768/2008/EC.

- c) requirements provisioned in Article R¹⁷ paragraph (4) in Annex I to Decision 768/2008/EC;
- d) not to be directly involved in the design, manufacture or building, marketing, installation, usage or maintenance of the radio equipment they assess, and does not represent the parties involved in those activities; the requirement also influences the top level management personnel and the personnel responsible for carrying out the conformity assessment tasks and shall be applied in particular to consultancy services;
- e) not to be involved in any activity that affect their impartiality or professional integrity in carrying out the conformity assessment activities for which they are notified; the requirement also influences the top level management personnel and the personnel responsible for carrying out the conformity assessment tasks and shall in particular apply to consultancy services;
- f) to ensure that the activities of their subsidiaries or subcontractors, as the case may be, do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities;
- g) to carry out the conformity assessment activities with professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly of financial nature, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities; the requirement also influences the personnel responsible for carrying out the conformity assessment activities;
- h) to be capable of carrying out all the conformity assessment tasks assigned in accordance with Annexes 3 and 4 in relation to which it was notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility;
- i) to have at its disposal, how many times is the case and for each conformity assessment procedure and for each type or category of radio equipment in relation to which it has been notified, the following:
 - 1) necessary personnel with technical knowledge and appropriate experience to perform the conformity assessment tasks;
 - 2) necessary descriptions of procedures in accordance with which the conformity assessment is carried out, ensuring the transparency and the possibility of reproduction of those procedures; the conformity assessment body shall have appropriate policies and procedures that make a clear distinction between the tasks it carries out as a notified body and the other/other activities;
 - 3) procedures necessary to carry out its activity which take due account of the size of an undertaking, the field of activity in which it operates and its structure, the degree of complexity of radio equipment technology in question and the mass or serial nature of the production process.

- j) to have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and to have access to all necessary equipment or facilities;
- k) to take part in information sessions, or to ensure that the personnel responsible for carrying out the conformity assessment tasks is informed on the relevant standardization activities, on the regulatory activities in the field of radio equipment and frequency planning, and on the activities of the notified bodies coordination group established under the Union relevant harmonisation legislation;
- l) to apply, as general guidance or guidelines, the decisions and documents that resulted from the activity provisioned at letter k);
- m) to ensure that the personnel responsible for carrying out the conformity assessment tasks shall comply with the requirements provisioned in paragraph (2);
- n) to guarantee the impartiality of the top level management personnel and of the personnel responsible for carrying out the conformity assessment tasks, and their remuneration shall not depend on the number of assessments carried out or on the results of those assessments;
- o) requirement provisioned in Article R¹⁷ paragraph (9) in Annex I to Decision 768/2008/EC.

(2) The personnel responsible for carrying out conformity assessment tasks shall:

- a) have a sustainable technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body was notified;
- b) to have satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
- c) to have appropriate knowledge and understanding of the essential requirements set out in accordance with Article 3, of the applicable harmonised standards, provisioned in Article 17 paragraph (1), and of the relevant provisions of the European Union harmonisation legislation and of national legislation;
- d) to have the necessary ability to draw up EU-type examination certificates, records and reports in order to demonstrate that the assessments were carried out.
- e) to fulfill the requirement set out in Article R¹⁷ paragraph (10) in Annex I to the Decision 768/2008/EC in the case of all information obtained as a result of fulfilling its tasks on the grounds of Annexes no. 3 and 4 or of any other provision in the national law on its enforcement, except the relationship with notification and market surveillance and radio equipment control authorities in the Member State where it operates; intellectual property rights are protected under the provisions of the applicable national law.

Article 27. – The requirements provided in Article 26 are considered to be met if the conformity assessment body demonstrates its compliance with the criteria set out in the relevant harmonised standards or parts thereof, the references of which have been published in the Official Journal of the European Union, but only to the extent that which the applicable harmonised standards cover these requirements.

Article 28. – (1) The conformity assessment body may decide, with the agreement of its client, to subcontract certain tasks on the conformity assessment or may call a branch.

(2) In the case under paragraph (1) the conformity assessment body takes into account the fulfillment of the following requirements:

- a) the subcontractor or the branch shall perform the tasks provisioned in Article 26 and shall inform MCSI accordingly;
- b) shall take full responsibility for the tasks performed by subcontractors or branches wherever these are established;
- c) shall keep at the disposal of MCSI the relevant documents concerning the assessment of the qualifications of the subcontractor or of the branch and the activities carried out by them on the grounds of Annexes no. 3 and 4.

Article 29. – (1) The notification application of the conformity assessment body submitted at MCSI, shall be accompanied by:

- a) a description of the conformity assessment activities, of the conformity assessment module or modules and of the radio equipment for which that body claims to be competent;
- b) an accreditation certificate, where such a certificate exists, issued by a national accreditation body, attesting that the conformity assessment body fulfils the requirements laid down in Article 26;

(2) Where the conformity assessment body is not able to provide an accreditation certificate provisioned in paragraph (1) letter b), it shall provide MCSI with all the justifying documents necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 26.

Article 30. – (1) MCSI may notify only conformity assessment bodies which have met all the requirements laid down in Article 26.

(2) The notification provisioned in paragraph (1) is forwarded to the European Commission and the competent authorities from other Member States of the European Union and European Economic Area using the electronic notification tool developed and managed by the European Commission.

(3) The notification shall include:

- a) full details of the conformity assessment activities, the conformity assessment module or modules and the radio equipment concerned, as well the relevant attestation of the competence of the conformity assessment body.
- b) justifying documents which attests the conformity assessment body competence and the measures taken to prove that the body will be monitored periodically and that it continues to meet the requirements laid down in Article 26, where the notification of the authority is not based on an accreditation certificate.

(4) The body is considered notified and may perform the activities for which it was notified, only there were no objections raised by the European Commission and other Member States of the European Union within:

- a) two weeks in case of use of an accreditation certificate;
- b) two months, for the situation provisioned in paragraph (3) letter b)

(5) MCSI shall notify the European Commission and the competent authorities from the other Member States of the European Union and European Economic Area of any subsequent relevant changes brought to the notification developed in accordance with the conditions set out in paragraphs (1)-(4).

Article 31. – (1) Where MCSI has ascertained, following the regular monitoring, or has been informed that a notified body no longer meets the requirements laid down in Article 26, or that it does not fulfill its obligations set out in accordance with Annexes no. 3 and 4, it shall restrict, suspend or withdraw the notification, as appropriate, depending on the seriousness of the failure to meet the requirements or to fulfill the obligations.

(2) In the event of any disposition of a measure of those referred to in paragraph (1), MCSI shall immediately inform the European Commission and the competent authorities from the other Member States of the European Union and European Economic Area.

(3) In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, MCSI shall take appropriate steps to ensure that the files of that body are:

- a) either processed by another notified body;
- b) or kept available for MCSI, ANCOM and/or ANPC, at the latter's request.

(4) The measures provided in paragraph (1) shall be arranged by the order of the Minister of Communications and Information Society, which will determine their type and duration. The order shall be published in the Official Journal of Romania, Part I, and may be challenged under Law no. 554/2004 on Administrative Litigations, with the subsequent amendments and completions.

Article 32. – If an investigation of the European Commission, according to the provisions of Article 33 paragraph (1) of Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the legislation of Member States relating to making available on the market of radio equipment and repealing Directive 1999/5/EC as regards competence of a notified body or the continued fulfilment by it of its requirements and responsibilities, MCSI shall forward, upon request, all information concerning the grounds of notification or the maintenance of the competence of the notified body concerned.

Article 33. – (1) Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided in Annexes 3 and 4, taking into account the provisions of paragraph (2).

(2) The conformity assessment bodies:

- a) shall perform their activity taking due account of the size of an undertaking, the field in which it operates, its structure, the degree of complexity of the radio equipment technology in question and the mass or serial nature of the production process;
- b) shall have to fulfill the degree of rigor and the level of protection required for the compliance of the radio equipment with the requirements of this decision;
- c) shall require the manufacturer to take appropriate corrective actions and shall not issue any EU-type examination certificate or a quality system approval notification, where it finds that the essential requirements set out in Article 3 or in corresponding

harmonised standards or in other suitable technical specifications have not been met by the manufacturer;

d) shall require the manufacturer to take appropriate corrective actions and shall suspend or withdraw the EU-type examination certificate or the quality system approval notification if necessary, where, in the course of the monitoring of conformity following their issue it finds that the radio equipment are no longer compliant.

(3) If no corrective measures are taken, according to paragraph (2) letters c) and d), or they do not have the necessary effect, the notified body restricts, suspends or withdraws any certificate, as the case may be. In this situation, the notified body shall inform MCSI, ANCOM, and/or ANPC, as the case may be.

Article 34. – The decisions of the conformity assessment bodies can be appealed to the court under the conditions of Law no. 554/2004, with the subsequent amendments and completions.

Article 35. – (1) The notified conformity assessment bodies have the obligation to inform MCSI on:

- a) any refusal, restriction, suspension or withdrawal of any EU-type examination certificate or any quality system approval notification in accordance with the requirements provisioned in Annexes no. 3 and 4;
- b) any circumstances that affect the scope or conditions of notification;
- c) any request for information regarding the conformity assessment activities carried out, received from the market surveillance and radio equipment control authorities;
- d) conformity assessment activities performed in the limit of the scope of notification and towards any other activity performed, including cross-border activities and cross-border subcontracting.

(2) The information provided in paragraph (1) letter d) is made available upon the request of MCSI.

(3) The notified bodies have the obligation to provide, in accordance with the requirements provisioned in Annexes 3 and 4, the other bodies notified at European Union level carrying out similar conformity assessment activities, covering the same categories of radio equipment, with relevant information on issues related to negative conformity assessments results.

(4) On request, the notified bodies have the obligation to provide the positive conformity assessments results.

(5) The notified bodies fulfil their information obligations in accordance with the provisions of Annexes 3 and 4.

Article 36. – Notified conformity assessment bodies have the obligation to participate, directly or through a designated representative, at the sectorial group of the notified bodies under the coordination of the European Commission.

Chapter V – Market surveillance

Article 37. – (1) The market surveillance and control activity, in order to fulfill the provisions of this decision and the obligations of the economic operators arising from European Union regulations, as well as in order to identify the traceability of radio equipment in the supply and distribution chain, is exercised by ANCOM and ANPC, hereinafter referred to as the market surveillance and radio equipment control authorities, that work by their specialized personnel, respectively specialized personnel empowered on this purpose.

(2) ANPC market surveillance and control activity regards the radio equipment conformity belonging to the consumer under conditions provisioned in Government Ordinance no. 21/1992 regarding Consumer Protection, republished, with the subsequent amendments and completions.

(3) ANCOM and ANPC organize and perform the market surveillance and control activity in accordance with the provisions of Article 15 paragraph (3) and Articles 16-29 of the Regulation (EC) no. 765/2008, including on radio equipment sold by electronic means, intended for the end-user, for his own use, and are subject to custom control.

(4) ANCOM and ANPC may conclude, on the purpose of enforcing this decision, a cooperation protocol which aims to ensure the exchange of information in order to improve measures to identify noncompliant products and undertake the necessary actions to eliminate them.

(5) In the surveillance and control activity, ANCOM and ANPC may request the National Institute for Research and Development in Informatics, in the case of the register of domains and sub-domains in the «.ro» field, to transmit the data or information that may lead to the identification of the persons who sell radio equipment through electronic means. The requested data are transmitted without delay to the market surveillance and radio equipment control authorities in accordance with the legal provisions regarding the protection of personal data.

Article 38. – (1) In the implementation of the provisions of this decision, the authorised personnel of ANCOM or ANPC, as the case may be, has the right to require from the economic operators or the end-users any information or documents necessary in order to exercise the powers relating to the market surveillance and radio equipment control.

(2) Persons provided in paragraph (1) have the obligation to make the information available to ANCOM or ANPC, as the case may be, under the terms and conditions specified by them.

Article 39. – is repealed.

Article 40. – (1) ANCOM or ANPC, according to their duties in accordance with the provisions of this decision, may decide at any time to carry out technical tests to check the conformity of radio equipment with the applicable essential requirements, based on standards or relevant technical specifications set out in the European Union declaration of conformity.

(2) If, in the European Union declaration of conformity, the respective technical standards or specifications are inappropriately provided or missing or the European Union declaration of conformity does not exist, the technical tests shall be performed on the basis of the harmonised standards provided in Article 17 paragraph (1).

Article 41. – (1) In order to perform technical tests according to the provisions of Article 40 paragraph (1), the manufacturer, the authorised representative, the importer or the

distributor, as the case may be, has the obligation to allow the control personnel to take, on the basis of a minute, free of charge, a representative number of samples of the radio equipment to be tested. Sampling can be ordered on the end-user radio equipment if there are indications that the radio equipment causes electromagnetic disturbances, harmful interference or presents a risk affecting the health and/or safety or property of persons.

(2) The expenses determined by carrying out the technical tests provided in Article 40 paragraph (1) are supported by ANCOM or ANPC from the annual budget approved on this purpose.

(3) Where following technical tests results that the radio equipment does not meet the essential requirements, the manufacturer or his authorised representative shall bear entirely the costs determined by carrying out the technical tests provided in Article 40 paragraph (1). Where the manufacturer or his authorised representative is not established on the national territory, the importer or the distributor, shall bear the costs entirely, as the case may be.

(4) In case the importer can not be identified or controlled economic operator does not provide any information that leads to his identification, the controlled economic operator shall bear the costs.

(5) With regard to the costs incurred by ANCOM, their individualization in order to establish the amount to be recovered in accordance with the provisions of paragraphs (3) or (4) is achieved by decision of the president of ANCOM, being applicable the provisions of Article 14 paragraph (2) of the Government Emergency Ordinance no. 22/2009 on the establishment of the National Authority for Management and Regulation in Communications, approved by Law no. 113/2010, with the subsequent amendments and completions.

(6) If the technical tests provisioned in Article 40 paragraph (1) are made in ANCOM's own laboratory, for the surveillance and control actions carried out by the specialized personnel of ANCOM, the provisions of paragraphs (3) and (4) do not apply.

(7) In order to perform the technical tests provisioned in Article 40 paragraph (1) the manufacturer or his authorised representative or the importer established on the national territory, as the case may be, has the obligation to make available to ANCOM or ANPC, as the case may be, at the request and within a deadline set by it, the software used by the manufacturer when carrying out his own technical tests performed to verify the fulfillment of the essential requirements.

Article 42. – (1) Subsequently to carrying out technical tests under the conditions set out in Articles 40 and 41, the radio equipment is returned to the person from whom it was taken.

(2) Where, due to technical tests performed on the radio equipment, it becomes unusable or is destroyed for reasons of exclusive fault of the personnel who carried out technical tests, the market surveillance and radio equipment control authority that has performed the technical tests shall bear the equivalent value of the radio equipment.

Article 43. – (1) f ANCOM or ANPC considers that radio equipment presents a risk that may affect the health or safety of persons or other aspects regarding the protection of the public interest protected by the provisions of this decision, it shall carry out an assessment regarding the radio equipment concerned.

(2) Assessment provisioned in paragraph (1), on all relevant requirements laid down in this decision, may be performed as a result of the technical tests provisioned in Article 40 paragraph (1), as well.

(3) The economic operators over which control actions are taken in accordance with the provisions of paragraphs (1) and (2) are under the obligation to cooperate at the request of the market surveillance and radio equipment control authorities.

(4) The assessment provided in paragraph (1) also takes into account, as the case may be, data on: the identified risks associated with the respective radio equipment, the possible data on the risks that have materialized in relation to the respective radio equipment or the measures taken by the concerned economic operator in order to mitigate the risks.

Article 44. – (1) Where, in the course of the assessment referred to in Article 43 paragraph (2), ANCOM or ANPC finds that the radio equipment does not comply with the requirements herein, the relevant economic operators are without delay required to take all necessary corrective actions to bring the radio equipment into compliance with those requirements and to limit its making available on the market or to withdraw the radio equipment from the market and/or to recall it within a reasonable term, commensurate proportionally with the nature of the risk, prescribed by ANCOM or ANPC, as the case may be.

(2) In the situation provided in paragraph (1), ANCOM or ANPC, as appropriate, shall inform the notified body that performed the compliance assessment of the measures taken.

(3) Provisions of Article 21 of the Regulation (EC) no. 765/2008 shall apply to the measures ordered in accordance with the provisions of paragraph (1).

(4) The corrective actions and restrictions provisioned under paragraph (1) are ordered by a decision of ANCOM President or by order of ANPC President, as the case may be.

Article 45. – If ANCOM or ANPC, as the case may be, considers that non-compliance of radio equipment affects the products that were or may be delivered on the territory of other Member States of the European Union or in the European Economic Area, it shall inform the European Commission and the market surveillance and radio equipment control authorities in the other states on the results of the evaluation and the actions which they imposed to the economic operator.

Article 46. – The economic operator against whom were ordered the measures provisioned in Article 44 has the obligation to apply the necessary corrective actions for all the radio equipment in question which he has made available on the market.

Article 47. – (1) If the economic operator does not take the corrective measures provisioned in Article 44 paragraphs (1) and (4), ANCOM or ANPC, as the case may be, takes all provisionally appropriate actions to prohibit or restrict the making available on the market of the radio equipment, to withdraw and/or recall it from the market. The measures are ordered by decision of ANCOM President or by order of ANPC President, as the case may be.

(2) The market surveillance and radio equipment control authority that ordered the measures shall notify, without delay, the European Commission and the market surveillance and radio equipment control authorities from the other Member States of the European Union

and European Economic Area on the provisional measures ordered in accordance with the provisions of paragraph (1).

- (3) Information provisioned in paragraph (2) shall include at least, the following:
 - a) data necessary to identify the non-compliant radio equipment;
 - b) the origin of the radio equipment;
 - c) the nature of the ascertained non-conformity and the risk involved;
 - d) the nature and duration of the national measures taken;
 - e) the arguments presented by the economic operator;
 - f) whether non-conformity is due to noncompliance with the relevant essential requirements provisioned in Article 3;
 - g) whether the non-conformity is due to the existence of some deficiencies on harmonised standards provisioned in Article 17 paragraph (1) which provide the presumption of conformity.
- (4) The measures provided in paragraph (1) shall be considered justified if no Member State or the European Commission has raised objections, within three months, with respect to the respective measures taken.
- (5) If the European Commission adopts an act by which establishes that the provisional measure(s) is/are not justified, the market surveillance and radio equipment control authorities shall withdraw the measures they ordered.
- (6) If the measures are considered justified, the market surveillance and radio equipment control authorities shall order that the provisional measures provided in paragraph (1) shall be applied permanently.

Article 48. – (1) Where, having carried out an assessment in accordance with Article 43 paragraph (2), finds that, although the radio equipment is in compliance with the requirements herein, it however presents a risk to the health or safety of persons or to other aspects of public interest protection covered by the provisions of this decision, ANCOM or ANPC, as the case may be, may require the relevant economic operator to take all corrective actions deemed necessary in order to ensure that the radio equipment concerned no longer presents that risk or to withdraw the radio equipment from the market and/or to recall it within a reasonable term, commensurate with the nature of the risk.

- (2) The economic operator has the obligation to take all appropriate corrective actions for all the radio equipment concerned that he has made available on the market.
- (3) The corrective actions provisioned in accordance with paragraphs (1) and (2) are ordered by a decision of ANCOM President or by order of ANPC President, as the case may be.
- (4) ANCOM or ANPC shall immediately inform the European Commission and the market surveillance and radio equipment control authorities in the other Member States of the European Union and the European Economic Area on the actions taken in accordance with the provisions of paragraph (1).
- (5) The information provisioned in paragraph (4) shall contain all available details, at least the data necessary for the identification of the respective radio equipment, the origin and the supply and distribution chain, the nature of the risk involved and the nature and duration of the national measures adopted.

Article 49. – Without excluding measures taken under Articles 43-48, ANCOM or ANPC may require the relevant economic operator to bring the radio equipment in conformity with the provisions of this decision, within maximum 15 calendar days, if it finds the following:

- a) the EC marking has been affixed contravening the Article 30 of Regulation (EC) No 765/2008 or Article 21 of this decision;
- b) the EC marking has not been affixed;
- c) the identification number of the notified body, if used the conformity assessment procedure provisioned in Annex no. 4, has been affixed contravening the provisions of Article 21 or has not been affixed;
- d) the EU declaration of conformity has not been drawn up;
- e) the EU declaration of conformity has not been drawn up correctly;
- f) the technical documentation is either not available or incomplete;
- g) the information referred to in Article 10 letters j) or k) or Article 13 letter e) is absent, false or incomplete;
- h) the information on the intended use of the radio equipment, the EU declaration of conformity or the usage restrictions as they are provisioned in Article 10 letters l), m) and n) does not accompany the radio equipment;
- i) the requirements provisioned in Article 16 on the identification of economic operators are not fulfilled;
- j) the provisions set out in Article 5 are not met.

Article 50. – ANCOM or ANPC staff, as the case may be, may decide to apply seals on radio equipment or on batches of radio equipment upon which measures have been ordered on the grounds of this decision.

Chapter VI – Contraventions and sanctions

Article 51. – (1) The following deeds are deemed contraventions, insofar they are not committed under such conditions that they might be considered, under the criminal law, offences:

- 1) the obligation provisioned in Article 10 letter a) was not fulfilled by not registering the radio equipment and not affixing by the manufacturer or his authorised representative thereof, as the case may be, of the registration number of radio equipment, under the conditions set out in Article 5;
- 2) the deed of the manufacturer to place on the market radio equipment that do not meet the essential requirements provisioned in Article 3, as provided in Article 10 letter b);
- 3) failure of the manufacturer to comply with the obligation to manufacture radio equipment so that it may operate without breaching the applicable requirements on the use of radio frequency spectrum, in accordance with the provisions of Article 10 letter c);
- 4) the manufacturer does to comply with the obligations under Article 10 letter d) to draw up the technical documentation pursuant to Article 23 or the obligation to perform the relevant conformity assessment procedure;

- 5) the manufacturer or his authorised representative, as the case may be, does not draw up the EU declaration of conformity, obligation provisioned in Article 10 letter e);
- 6) the manufacturer or his authorised representative, as the case may be, does not affix the EC marking, in accordance with the obligation under Article 10 letter e);
- 7) the manufacturer or his authorised representative, as the case may be, does not comply with the obligation provisioned in Article 10 letter f) to keep the technical documentation and the EU declaration of conformity for 10 years after the radio equipment was placed on the market;
- 8) the manufacturer or his authorised representative, as the case may be, does not comply with the obligation provisioned in Article 10 letter g);
- 9) the manufacturer or his authorised representative, as the case may be, or importer does not comply with the obligation provisioned in Article 10 letter h), respectively in Article 13 letter h) to carry out, through survey, the technical tests on radio equipment made available on the market, investigate and keep a register of complaints on noncompliant radio equipment and its recalls;
- 10) the manufacturer or his authorised representative, as the case may be, to comply with the obligation provisioned in Article 10 letter i) to inform the distributors on monitoring activities performed according to Article 10 letter h);
- 11) the deed of the manufacturer or his authorised representative to place on the market apparatus on which the elements were not affixed or is not accompanied by the information provisioned in Article 10 letter j);
- 12) the manufacturer or his authorised representative, as the case may be, or the importer does not comply with the obligation provisioned in Article 10 letter k) , respectively, in Article 13 letter e), to indicate on the radio equipment the name, registered trade name or registered trade mark and the postal address;
- 13) the manufacturer or his authorised representative, as the case may be, does not comply with the obligation provisioned in Article 10 letter l) to supply with the instructions and information on the radio equipment safety, with compliance of the requirements provisioned in Article 11;
- 14) the manufacturer or his authorised representative, as the case may be, does not comply with the obligation provisioned in Article 10 letter m) to ensure that each radio equipment is accompanied by a copy of the EU declaration of conformity or a copy of the simplified EU declaration of conformity;
- 15) the manufacturer or his authorised representative, as the case may be, does not comply with the obligation provisioned in Article 10 letter n) to indicate on the packaging of radio equipment and in the usage instructions, the restrictions on putting into service or the areas or the geographical regions where an authorisation is required for the use of radio equipment;
- 16) failure of the controlled economic operator to take, immediately, any necessary corrective measure to bring that apparatus into conformity, to withdraw it or recall it, as the case may be, where he holds indications or information that an apparatus he placed on the market and/or made available on the market is not compliant with the provisions of this decision, in accordance with the provisions of Article 10 letter o) and Article 13 letter j), respectively to immediately inform the market surveillance and radio equipment

- control authorities, under the conditions provisioned in Article 10 letter p) and Article 13 letter j), or to ensure the fulfillment of the obligation established according to the provisions of Article 14 letter e), as the case may be;
- 17) failure of the controlled economic operator to take the measures provisioned under Article 47 paragraph (1), under conditions set out in Article 47 paragraph (6) or to comply with the requirement set out in Article 46 or Article 48 paragraph (2);
 - 18) failure of the economic operator to comply with the obligation to provide the information and documentation requested by ANCOM or ANPC, as the case may be, under the conditions set out in Article 10 letter q), Article 12 paragraph (3) letter b), Article 13 letter l) or Article 14 letter f);
 - 19) the controlled economic operator does not comply with the obligation provisioned in Article 10 letter r), Article 13 letter m) or Article 14 letter g) to cooperate with the market surveillance and radio equipment control authorities regarding the actions taken to eliminate the risks posed by the radio equipment which they have placed on the market or made available on the market;
 - 20) failure of the controlled economic operator to comply with the obligation set out in Article 16 to provide the requested identification data or with the obligation set out in Article 38 to provide the necessary information in order for the duties related to the market surveillance to be exercised;
 - 21) the importer does not comply with the obligation provisioned in Article 13 letter a) to ensure that the radio equipment placed on the market are compliant with the provisions of this decision;
 - 22) the importer does not comply with the obligation provisioned in Article 13 letter b) to verify, before placing on the market the radio equipment, the compliance of the manufacturer with the conformity assessment procedure provided in Articles 18 and 19;
 - 23) failure of the importer to comply with the obligation to ensure, before being placed on the market, that the radio equipment is manufactured so that it may operate without breaching the applicable requirements on the use of radio spectrum established in accordance with the law, under the provisions of Article 13 letter b);
 - 24) the importer does not comply with the obligation set out in Article 13 letter c) to verify that the manufacturer fulfilled his obligation to draw up the technical documentation or that the manufacturer affixed the EC marking on the radio equipment;
 - 25) the importer does not comply with the obligation set out in Article 13 letter c) to verify that the manufacturer fulfilled his obligations in accordance with Article 10 letters j)-n);
 - 26) failure of the importer to comply with the obligation set out in Article 13 letter d) not to place radio equipment on the market before they are brought into conformity with the provisions of this decision, where he holds indications or information that the radio equipment is not compliant with the essential requirements, or with the obligation to inform the manufacturer and the market surveillance and radio equipment control authorities when the radio equipment poses a risk;
 - 27) the deed of the importer or distributor to jeopardize the compliance of the radio equipment with the essential requirements due to its inappropriate storage or transport conditions, obligation which is provisioned in Article 13 letter g), respectively in Article 14 letter d);

- 28) the importer does not comply with the obligation provisioned in Article 13 letter i) to inform the distributor on the performance of the monitoring activities;
- 29) the importer does not comply with the obligation provisioned in Article 13 letter k) to keep the EU declaration of conformity for 10 years after the radio equipment has been placed on the market;
- 30) the distributor does not comply with the obligation provisioned in Article 14 letter a) to ensure that the way he makes the radio equipment available on the market is not of nature to affect the essential requirements;
- 31) the distributor does not comply with the obligation provisioned in Article 14 letter b) to verify, before the radio equipment is made available on the market, whether the radio equipment bears the EC marking or is accompanied by the documents provisioned in this decision;
- 32) the distributor does not comply with the obligation provisioned in Article 14 letter b) to verify whether the manufacturer complied with the obligations provisioned in Article 10 letter c), letters j) - n), meeting the requirements provisioned in Article 11 in the case of the obligation provisioned in Article 10 letter l) and, respectively, whether the importer complied with the obligation provisioned in Article 13 letter e);
- 33) failure of the distributor to comply with the obligation not to make available on the market the radio equipment until it has been brought into conformity with the provisions of this decision, where he holds indications or information that the radio equipment does not comply with the essential requirements, or with the obligation to inform the manufacturer or the importer and the market surveillance and radio equipment control authorities when the radio equipment presents a risk in accordance with the provisions of Article 14 letter c);
- 34) the economic operators or the end-user does not comply with the obligation provisioned in Article 41 paragraph (1) to allow to carry out sample testing of radio equipment in order to submit them to technical tests;
- 35) to display, by any person and/or demonstrations with noncompliant radio equipment at trade fairs, exhibitions and similar events, without complying with the provisions of Article 6 paragraphs (2) and (3);
- 36) the radio equipment and software manufacturers do not comply with the requirement provisioned in Article 4 to submit to ANCOM information on the compliance of radio equipment-software combinations;
- 37) the conformity assessment bodies do not comply with the obligations provisioned in Article 28 paragraph (2) letters a) and c);
- 38) the conformity assessment bodies do not comply with the obligations provisioned in Article 35 paragraphs (1), (3) and (4);
- 39) the deed of the manufacturer or of his authorised representative, as the case may be, to affix the EC marking without complying with the provisions of Article 21;
- 40) the deed of any person to manufacture, have, import, advertise, place or make available on the market or use radio equipment or devices designed to create harmful interferences, obligation provisioned in Article 9 paragraph (2);

- 41) refusal of the end-user to provide the market surveillance and radio equipment control authority, according to provisions set out in Article 38, with the necessary data and/or information in order to check the compliance with the provisions of this decision;
 - 42) the deed of the importer or the distributor to place on the market, respectively to make available on the market an equipment in case of the EC marking does not comply with the provisions of Article 21;
 - 43) the deed of the notified body, manufacturer or his authorised representative, as the case may be, not to affix the identification number of the notified body, under conditions set out in Article 21 paragraph (6);
 - 44) non-compliance by the holder of the license granted according to the law of the obligation established according to Article 7 paragraph (4);
 - 45) failure of the holder of the license granted according to the law to provide the information requested according to the provisions of Article 7 paragraphs (5) and (7), under conditions set out in Article 7 paragraph (6);
 - 46) the manufacturer or importer, as the case may be, does not comply with the obligation provisioned in Article 41 paragraph (7) to provide with the software used on the occasion of carrying out the technical tests developed to verify the fulfillment of the essential requirements;
 - 47) the economic operators do not comply with the requirement provisioned in Article 49;
 - 48) the deed of the end-user to put into operation and/or use the radio equipment which is non-compliant with Article 6 paragraph (1).
- (2) The contraventions identified under paragraph (1) shall be sanctioned as follows:
- 1) in the case of the contravention provisioned in point 1, with fine ranging from RON 2,500 to RON 10,000;
 - 2) in the case of the contraventions provisioned in points 2 and 3, with fine ranging from RON 10,500 to RON 50,000;
 - 3) in the case of the contravention provisioned in point 4, with fine ranging from RON 5,000 to RON 20,000;
 - 4) in the case of the contraventions provisioned in points 5 and 6, with fine ranging from RON 5,500 to RON 30,000;
 - 5) in the case of the contraventions provisioned in points 7 and 8 and point 29, with fine ranging from RON 2,500 to RON 20,000;
 - 6) in the case of the contraventions provisioned in points 9 and 10, with fine ranging from RON 10,000 to RON 35,000;
 - 7) in the case of the contraventions provisioned in points 11 and 12, with fine ranging from RON 5,000 to RON 25,000;
 - 8) in the case of the contraventions provisioned in points 13 and 14, with fine ranging from RON 2,500 to RON 25,000;
 - 9) in the case of the contravention provisioned in point 15, with fine ranging from RON 2,500 to RON 35,000;
 - 10) in the case of the contraventions provisioned in points 16-20 and point 36, with fine ranging from RON 10,000 to RON 50,000;
 - 11) in the case of the contraventions provisioned in points 21-23, with fine ranging from RON 2,500 to RON 25,000;

- 12) in the case of the contraventions provisioned in points 24 and 25, with fine ranging from RON 5,500 to RON 25,000;
- 13) in the case of the contraventions provisioned in point 26 and point 33, with fine ranging from RON 7,500 to RON 35,000;
- 14) in the case of the contravention provisioned in point 27, with fine ranging from RON 2,500 to RON 25,000;
- 15) in the case of the contravention provisioned in point 28, with fine ranging from RON 2,500 to RON 15,000;
- 16) in the case of the contravention provisioned in point 30, with fine ranging from RON 5,000 to RON 35,000;
- 17) in the case of the contraventions provisioned in points 31 and 32, with fine ranging from RON 2,500 to RON 22,500;
- 18) in the case of the contravention provisioned in point 34 and point 42, with fine ranging from RON 10,000 to RON 50,000;
- 19) in the case of the contravention provisioned in point 35, with fine ranging from RON 10,000 to RON 40,000;
- 20) in the case of the contraventions provisioned in points 37-39 with fine ranging from RON 20,000 to RON 50,000;
- 21) in the case of the contravention provisioned in point 40, with fine ranging from RON 15,000 to RON 50,000;
- 22) in the case of the contraventions provisioned in point 41 and points 46-48, with fine ranging from RON 500 to RON 5,000;
- 23) in the case of the contravention provisioned in point 43, with fine ranging from RON 7,500 to RON 30,000;
- 24) in the case of the contraventions provisioned in points 44 and 45, with fine ranging from RON 2,500 to RON 50,000.

Article 52. – (1) The contraventions provisioned by this decision shall be assessed by the control personnel of the market surveillance and radio equipment control authorities, by means of the official report establishing the contravention and applying the sanction.

- (2) The sanctions for the contraventions provisioned by this decision shall be applied as follows:
- a) by means of the official report establishing the contravention and applying the sanction by the specialised personnel of ANCOM for the contraventions identified under Article 51 paragraph (1) points 1, 9, 10, 16, 17, 19, 26-28, 30, 33, 35, 36, 41 and 43-46;
 - b) by means of written resolution of the president of ANCOM, inscribed on the official report establishing the contravention and applying the sanction for the contraventions assessed by the personnel of ANCOM, in those cases referred to in Article 51 paragraph (1) points 2-8, 11-15, 18, 20-25, 29, 31, 32, 34, 39, 40, 42, 47 and 48;
 - c) by means of the official report establishing the contravention and applying the sanction by the ascertaining agent, for the contraventions assessed by ANPC personnel, in those cases referred to in Article 51 paragraph (1) points 2, 16-21, 26, 33, 34, 40, 41 and 48, where the radio equipment was purchased by the consumer;

- d) by means of the official report establishing the contravention and applying the sanction by empowered staff of MCSI, in those cases referred to in Article 51 paragraph (1) points 37-38.

Article 53. – (1) ANCOM or ANPC, as the case may be, may also order by means of the official report establishing the contravention and applying the sanction, the following additional sanctions:

- a) the use of the equipment is banned until it is brought in compliance with the essential requirements, for the deed provisioned under Article 51 paragraph (1) point 48;
- b) confiscation, in the case of the deed provisioned under Article 51 paragraph (1) point 40, under conditions set out in Article 5 paragraph (3) letter a) of the Government Ordinance no. 2/2001 on the legal regime of contraventions, approved with amendments and completions by Law no. 180/2002, with the subsequent amendments and completions.

(2) The additional sanctions provisioned under paragraph (1) shall be applied by the persons and by observing the procedure specified according to Article 52 paragraph (2) letters b) and c).

Article 54. – Contraventions provisioned in this decision are under the provisions of the Government Ordinance no. 2/2001 on the legal regime of contraventions, approved with amendments and completions by Law no. 180/2002, with the subsequent amendments and completions.

Chapter VII - Final and transitional provisions

Article 55. – Annexes no. 1 - 7 are part of this decision.

Article 56. – (1) Market surveillance and radio equipment control authorities shall submit to the European Commission regular reports by 12 June 2017 and at least, every two years thereafter.

(2) The reports provisioned under paragraph (1) shall contain a presentation of the market surveillance activities and provide information on the compliance of radio equipment with the requirements of this decision, including requirements on identification of economic operators.

Article 57. – Radio equipment covered by this decision which was placed on the market until 13 June 2017 and are compliant with the essential requirements provisioned under Government Decision no. 130/2015 on radio equipment and electronic communications terminal equipment and the mutual recognition of their conformity are allowed to be placed on the market and/or put into service¹.

¹ In the case of Article 57 a transitional measure was adopted through Article III paragraph (2) of the Government Decision no. 431 of 20 June 2019, amending and completing Government Decision no. 487/2016 regarding the electromagnetic compatibility and the Government Decision no. 740/2016 on the making available on the market of radio equipment, which stipulates the following: "The radio equipment placed on the market prior to 13 June 2017 and which meets the provisions of Government Decision no. 130/2015 on the radio equipment and the

Article 58. – (1) The present decision shall enter into force within 30 days after it is published in the Official Journal of Romania, Part I.

(2) The Government Decision no. 130/2015 on radio equipment and electronic communications terminal equipment and the mutual recognition of their conformity published in the Official Journal of Romania, Part I, no. 202 as of 26 March 2015 is hereby repealed as from the date the present decision enters into force.

(3) Whenever another previously law refers to the repealed law in paragraph (2) the reference shall be deemed to be made to the corresponding provisions of this decision.

The present decision transposes 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 the radio equipment and repealing Directive 1999/5/EC, published in the Official Journal of the European Union (JOUE) series L, no. 153 of 22 May 2014.

electronic communications terminal equipment and the mutual recognition of their conformity may be made available on the market and/or put into service.

Equipment not covered by this decision

1. Radio equipment used by radio amateurs within the meaning of Article 1, definition 56, of the International Telecommunications Union 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 intended to be assembled and used by radio amateurs;
 - b) radio equipment modified by radio amateurs and intended for their own use;
 - c) radio equipment developed by radio amateurs acting individually for scientific and experimental purposes in the radio amateurs activity.
2. The maritime equipment that falls within the scope of the Government Decision no. 494/2006 on maritime equipment, with the subsequent amendments and completions.
 3. The following airborne products, where they fall within the scope of Regulation (EU) 2018/1.139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) no. 2.111/2005, (EC) no. 1.008/2008, (EU) no. 996/2010, (EU) no. 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) no. 552/2004 and (EC) no. 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) no. 3.922/91 and are intended for in-flight use only:
 - a) aircrafts, other than unmanned aircrafts, as well as their engines, propellers, parts and non-installed equipment;
 - b) unmanned aircrafts, as well as their engines, propellers, parts and non-installed equipment whose design is certified in accordance with Article 56 paragraph (1) of Regulations (EU) 2018/1.139 and which are intended for operation exclusively on assigned radio frequencies, in accordance with the Radio Regulations of the International Telecommunications Union, for protected aeronautical use.
 4. Custom-built evaluation kits for professionals to be used solely at research and development facilities for such purposes.

Module A of conformity assessment

Internal production control

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2-4 and ensures and declares on his sole responsibility that the radio equipment concerned satisfies the essential requirements set out in Article 3 of this decision.
2. Technical documentation
The manufacturer shall establish the technical documentation in accordance with the provisions of Article 23 of this decision.
3. Manufacturing
The manufacturer shall take all measures necessary that the manufacturing process and its monitoring ensure the compliance of the manufactured radio equipment with the technical documentation referred to in point 2 and with the relevant essential requirements set out in Article 3 of this decision.
4. The EC marking and the EU declaration of conformity
 - 4.1. The manufacturer shall affix the EC marking in accordance with the provisions of Article 21 of this decision, to each radio equipment item that meets 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 market surveillance and radio equipment control 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 by the manufacturer to the market surveillance and radio equipment control authorities upon their request.
5. The 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.

Conformity assessment modules B and C

Module B – EU-type examination

1. EU-type examination is that part of the conformity assessment procedure in which a notified body examines the technical design of the radio equipment, verifies and attests if the technical design of the radio equipment meets the essential requirements set out in Article 3 of this decision.
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 documentation referred to in point 3, without examination of a sample (design type).
3. The manufacturer shall submit an application for EU-type examination to a single notified body at his choice.

The application shall include:

- a) the name and address of the manufacturer and, if the application is submitted by the authorised representative, his name and address as well;
- b) a written declaration on his sole responsibility to attest that the same application has not been submitted to any other notified body.

The application shall be accompanied by:

- a) the technical documentation. The technical documentation shall make possible to assess the radio equipment's conformity with the applicable requirements of this decision and shall include an adequate analysis and assessment of the risks. The technical documentation shall specify the applicable requirements and cover, as far as it is relevant for the assessment, information on the design, manufacture and operation of the radio equipment. The technical documentation shall contain, wherever applicable, the elements set out in Annex no. 5;
 - b) the justifying documents for the adequacy of the technical design solution. That justifying documents shall mention all the documents that have been used, in particular where the relevant harmonised standards have not been fully applied or have not been applied. The justifying documents shall include, where necessary, the results of technical tests carried out in accordance with other relevant technical specifications, by the appropriate laboratory of the manufacturer, or by another testing laboratory on behalf of the manufacturer and under his responsibility.
4. The notified body shall examine the technical documentation and justifying documents to assess the adequacy of the technical design of the radio equipment.
 5. The notified body shall draw up an assessment report that highlights 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 not release the content of

that report, in full or in part, if the manufacturer did not give its agreement on this issue.

6. Where the radio equipment type meets the requirements of this decision, the notified body shall issue an EU-type examination certificate to the manufacturer. This 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 assessment of 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 decision, 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 informed on any changes in the generally acknowledged state of the technology which indicates that the approved type may no longer comply with the applicable requirements of this decision, and shall determine whether such changes require extra investigations. 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 of the approved type that may affect the conformity of the radio equipment with the essential requirements or the conditions for validity of that certificate. Such changes shall require additional approval in the form of an addition to the original EU-type examination certificate.

8. Each notified body shall inform MCSI 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 the European Union and of the European Economic Area on the EU-type examination certificates it has issued and/or any 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 not been fully applied or have not been applied.

The European Commission, the Member States of the European Union and of the European Economic Area and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the European Commission and the Member States of the European Union and of the European Economic Area 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 market surveillance and radio equipment control authorities for 10 years after the radio equipment has been placed on the market.
10. The manufacturer's authorised representative may submit 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 C - Conformity to type based on internal production control

1. Conformity to type based on internal production control is that 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 decision.
2. Manufacturing
The manufacturer shall take all measures necessary that the manufacturing process and its monitoring ensure the conformity of the manufactured radio equipment with the approved type described in the EU-type examination certificate and with the requirements of this decision.
3. EC marking and EU declaration of conformity
 - 3.1. The manufacturer shall affix the EC marking in accordance with the provisions of Article 21 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 decision.
 - 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 market surveillance and radio equipment control 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 market surveillance and radio equipment control authorities upon their 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.

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 3, and ensures and declares on his sole responsibility that the radio equipment concerned satisfies the requirements of this decision.

2. Manufacturing

The manufacturer shall operate an approved quality system for design, manufacture, finished radio equipment final 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 submit an assessment application of his quality system to 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 submit by his authorised representative, his name and address as well;
- b) a written declaration that testify the same application has not been submitted to any other notified body.

The application shall be accompanied by:

- a) 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 no. 5;
- b) the documentation concerning the quality system.

3.2. The quality system shall ensure compliance of the radio equipment with the requirements of this decision.

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 programs, plans, manuals and records or quality evidences.

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

- a) the quality objectives, the organizational structure and 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 decision that apply to the radio equipment will be met;
- c) the design control and design verification techniques, procedures 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, procedures 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 on the applicable requirements of this decision. The audit shall include an assessment visit to the manufacturer's premises. The audit team shall analyze the technical documentation referred to in point 3.1 paragraph 3 letter a) to verify the manufacturer's ability to identify the applicable requirements of this decision 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 on the assessment decision. The notification shall include the conclusions of the audit and the duly motivated assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising from the approved quality system and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall inform the notified body that has approved the quality system on any intended change to the quality system.

The notified body shall assess 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, notifying the manufacturer on 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) quality evidences or records as provided for the quality system, such as: results of analyses, calculations, tests, etc.;
- c) quality evidences or records as provided for the manufacturing part of the quality system, such as: inspection reports, test data, calibration data, reports concerning the qualifications of the personnel, and the like.

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. The notified body may pay unexpected visits to the manufacturer headquarter. During such visits, the notified body may, if it is necessary, carry out radio equipment technical 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 EC marking in accordance with Article 21 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 meets the applicable requirements set out in Article 3 of this decision.

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 market surveillance and radio equipment control 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 market surveillance and radio equipment control authorities upon their request.

6. The manufacturer shall keep at the disposal of the market surveillance and radio equipment control authorities, for a period ending 10 years after the radio equipment has been placed on the market, the following:

- a) the technical documentation referred to in point 3.1 paragraph 3 letter a);
- b) the documentation concerning the quality system referred to in point 3.1 paragraph 3 letter b);
- 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 MCSI on the issued or withdrawn quality system approval notices, and, periodically or upon request, shall make available to it the list of refused, suspended or otherwise restricted quality system approval notices.

Each notified body shall inform the other notified bodies on the quality system approval notices which it refused, suspended or withdrew, and, upon request, on the quality system approvals notices which it 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.

Contents of technical documentation

The technical documentation shall contain, as the case may be, at least the following elements:

- a) a general description of the radio equipment including:
 - i) photos or illustrations showing external features, marking and internal layout;
 - ii) versions of software or firmware affecting compliance with the essential requirements;
 - iii) user information and installation instructions;
- b) conceptual design, manufacturing drawings and schemes of components as well, sub-assemblies, circuits and other relevant similar elements;
- c) descriptions and explanations necessary for the understanding of the drawings and schemes above mentioned and the operation of the radio equipment, as well;
- 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 of this decision, including a list of other relevant technical specifications applied. In the event that the harmonised standards were partly applied, the technical documentation shall specify the parts which have been applied;
- e) a copy of the EU declaration of conformity;
- f) where the conformity assessment module provisioned in Annex 3 was applied, a copy of the EU type examination certificate and its annexes, as delivered by the notified body involved;
- g) results of the design calculations made, examinations carried out, and other relevant similar elements;
- h) test reports;
- i) an explanation on the compliance with the requirement provisioned in Article 10 letter c) and the inclusion or not of information on the packaging in accordance with the provisions of Article 10 letter n).

EU Declaration of conformity no. (YYYY)²

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 was issued under the sole responsibility of the manufacturer.
4. Object of the declaration (identification of the radio equipment allowing traceability; it may include a color image, clear enough where it is necessary for the identification of the radio equipment): ...
5. The object of the declaration described above is compliant with the relevant European Union harmonisation legislation:
 - Directive 2014/53/EU
 - other European Union harmonisation legislation documents (where applicable)
6. References to the used relevant harmonised standards or references to the other technical specifications in relation to which conformity is declared. References shall be listed with their identification numbers and version and, where applicable, with the 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, a description of accessories and components, including software, which allow the radio equipment to operate as intended and are included in the EU declaration of conformity: ...
9. Additional information:
Signed for and on behalf of: ... place and date of issue: ... name, function, signature: ...

⁽²⁾ It is optional for the manufacturer to assign a number to the EU declaration of conformity.

Simplified EU declaration of conformity

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

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

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

...