

**Obligations of the economic operators
(according to the Government Decision no. 487/2016,
unofficially consolidated text containing the provisions
coming into force from 8 August 2019)**

Article 6

MANUFACTURERS have the following obligations:

- a)** to ensure that the devices they place on the market are designed and manufactured in accordance with the essential requirements set out in Annex no. 1;
- b)** to draw up the technical documentation referred to in Annex no. 2 or Annex no. 3 and carry out the relevant conformity assessment procedure referred to in Article 13 or to delegate the authorised representative to carry it out;
- c)** to draw up the EU declaration of conformity according to the provisions of Article 14 and to affix the EC marking, if the compliance of the device with the applicable requirements by the relevant conformity assessment procedure mentioned in Article 13 was demonstrated;
- d)** to keep the technical documentation and the EU declaration of conformity for 10 years after the apparatus has been placed on the market;
- e)** to ensure that there are procedures that ensure the continuous conformity of the production in series with the provisions of this decision;
- f)** to ensure that changes in apparatus design or those on its characteristics and changes in the harmonised standards, provisioned in Article 12 paragraph (1), or changes in other technical specifications by reference to which conformity of the apparatus is declared, shall be properly taken into account;
- g)** to ensure that apparatus which they place on the market bear the type, batch or serial number or other element allowing their identification, or, where the size or nature of the apparatus does not allow it, that the required information is provided on the packaging or in a document accompanying the apparatus;
- h)** to indicate, on the apparatus, the name, registered trade name or registered trade mark and the postal address at which they may be contacted or, where that is not possible, on the packaging or in a document accompanying the apparatus; the address mentioned by the manufacturer shall indicate a single contact point and the contact details shall be clear, accessible, intelligible, relevant and in Romanian;
- i)** to ensure that the apparatus is accompanied by the instructions and the information referred to in Article 16 written in Romanian; the instructions and information, as well as any texts printed on labels, shall be clear, accessible, intelligible and relevant;
- j)** to take immediately any corrective measures necessary to bring that apparatus into conformity, to withdraw it and/or recall it, as the case may be, if they hold clues or information that an apparatus which they placed on the market is not compliant with the provisions of this decision;
- k)** to inform immediately the competent authorities of the Member States where the device was made available on the market, if they find that the device presents a risk which may affect its operation or the operation of other equipment or for safety reasons, mentioning the details, especially, regarding non-compliance and any corrective measures taken;

- l)** further to a reasoned request from the market surveillance and control authorities, and within the term set by them, to provide, in paper or electronic form, all the information and documentation necessary to demonstrate the conformity of the apparatus with the provisions of this decision, presented in Romanian or in English language;
- m)** to cooperate with market surveillance and control authorities, upon their request, on any action taken in view of eliminating the risks posed by the apparatus which they have placed on the market;
- n)** to inform the notified body that holds the technical documentation relating to the EU-type examination certificate on all changes of the approved type that may affect the compliance of the apparatus with the essential requirements of this decision or with the validity conditions of that certificate.

Article 7

(1) A manufacturer may, by a written mandate, appoint an authorised representative.

(2) The obligations laid down in Article 6 letter a) and the obligation to draw up technical documentation referred to in Article 6 letter b) shall not form part of the authorised representative's mandate.

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

- 1.** to keep the EU declaration of conformity and technical documentation at the disposal of the market surveillance and control authorities for 10 years after the device has been placed on the market;
- 2.** further to a reasoned request from the market surveillance and control authorities, to provide, in paper or electronic form, all the information and/or documentation necessary to demonstrate the conformity of the apparatus, presented in Romanian or in English language;
- 3.** to cooperate with the market surveillance and control authorities, upon request, on any action taken in view of eliminating the risks posed by the apparatus falling under the obligations specified in the mandate of the authorised representative.

Article 8

IMPORTERS have the following obligations:

- 1.** to place on the market only compliant apparatus;
- 2.** before placing apparatus on the market, to ensure that the appropriate conformity assessment procedure referred to in Article 13 has been carried out by the manufacturer;
- 3.** to ensure that the manufacturer has drawn up the technical documentation, that the apparatus bears the EC marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 6 letters g)-h);
- 4.** if there are clues or information to believe that the apparatus is not compliant with the essential requirements set out in Annex I, until it has been brought into

conformity and for safety reasons, to inform the manufacturer and the market surveillance and control authorities;

5. to indicate on the apparatus their name, registered trade name or registered trade mark and the postal address at which they may be contacted or, where that is not possible, on its packaging or in a document accompanying the apparatus; the contact details shall be clear, accessible, intelligible, relevant and presented in Romanian language;

6. to ensure that the apparatus is accompanied by instructions and the information referred to in Article 16; instructions and information shall be in Romanian, accessible, intelligible, correct and complete;

7. to ensure that, while apparatus is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex I;

8. to take immediately any necessary corrective action to bring the apparatus into conformity, to withdraw it and/or to recall it, as the case may be, if there are clues or information that a device placed on the market does not comply with the provisions of this decision;

9. to inform immediately the competent authorities of the Member States where the apparatus was made available on the market, if it presents a risk which may affect its operation or the operation of other equipment or for safety reasons, mentioning details, in particular, on non-compliance and any corrective measures taken;

10. to keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities for 10 years after the apparatus has been placed on the market, and ensure that the technical documentation can be made available to those authorities, upon request;

11. further to a reasoned request from the market surveillance and control authorities and within the term set by them, to provide, in paper or electronic form, all the information and documentation necessary to demonstrate the conformity of the apparatus with the provisions of this decision, presented in Romanian or in English language;

12. to cooperate with the market surveillance and control authorities, upon request, on any action taken to eliminate the risks posed by the apparatus which they have placed on the market.

Article 9

DISTRIBUTORS have the following obligations:

1. to ensure that the way in which apparatus is made available on the market is not likely to affect the essential requirements established by this decision.

2. before making apparatus available on the market, to ensure that the apparatus bears the EC marking, that it is accompanied by the required documents, instructions and information referred to in Article 16, drawn up in Romanian;

3. to ensure that the manufacturer and the importer have complied with the requirements set out in Article 6 letters g)-h) and Article 8 point 5;

4. not to make the apparatus available on the market, if there are clues or information that the apparatus does not comply with the essential requirements set out in Annex no. 1, before it is brought into conformity and, for safety reasons, to inform the manufacturer or importer, as well as the market surveillance and control authorities;

- 5.** to ensure that, while apparatus is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex I;
- 6.** to ensure that any corrective measures necessary to bring that apparatus into conformity or to withdraw it and/or recall it, as the case may be, are taken, when they have indications or information that an apparatus that they have made available on the market does not comply with the provisions of this decision;
- 7.** to inform immediately the surveillance and control authorities of the Member States where the apparatus was made available on the market, if it presents a risk that may affect its operation or the operation of other equipment or for safety reasons, mentioning the details in especially, regarding non-compliance and any corrective measures taken;
- 8.** to provide, further to a reasoned request from the market surveillance and control authorities, and within the term set by them, in paper or electronic form, all the information and documentation necessary to demonstrate the conformity of the apparatus with the provisions of this decision, presented in Romanian or in English language;
- 9.** to cooperate with the market surveillance and control authorities, at their request, on any action taken to eliminate the risks posed by apparatus which they have made available on the market.

Article 10

The importer or the distributor shall be considered a manufacturer for the purposes of this decision and he shall be subject to the obligations of the manufacturer under Article 6, where he places apparatus on the market under his name or trade mark or modifies an apparatus already placed on the market in such a way that compliance with this decision may be affected.

Article 11

- (1)** Economic operators shall, on request, identify the following to the market surveillance authorities:
 - a)** any economic operator who has supplied them with apparatus;
 - b)** any economic operator to whom they have supplied apparatus.
- (2)** Economic operators shall be able to keep and present the information referred to in the first paragraph for 10 years after the apparatus was supplied or after they supplied the apparatus.