

**DRAFT COMMISSION DELEGATED REGULATION (EU) .../...**  
**of XXX**

**on making available on the market of unmanned aircraft intended for use in the ‘open’  
category and on third-country UAS operators**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) .../... [new BR] of the European Parliament and of the Council on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Regulation (EC) No 216/2008 <sup>(1)</sup>, and in particular Articles 45, 46, 47, 48, 50 and 51 thereof,

Whereas:

- (1) The UAS intended to be operated in the ‘open’ category covering operations presenting the lowest risks should not be subject to classic aeronautical compliance procedures. For those consumer products, the possibility to establish ‘Union harmonisation legislation’ provided for by Article 46.3 of Regulation (EU) .../... [new BR] should be used. This Regulation should, in consequence, set out the requirements that address the risk posed by operation of those UAS, taking full account of other applicable EU harmonisation legislation.
- (2) Unmanned aircraft and their engines, propellers, parts and non-installed equipment within the scope of Regulation (EU) .../... [new BR] and intended exclusively for airborne use are excluded from the scope of Directive 2014/53/EU <sup>(2)</sup> and Directive 2014/30/EU <sup>(3)</sup> only from the moment and in as far as the design of the unmanned aircraft and of their engines, propellers, parts and non-installed equipment are certified in accordance with Regulation (EU) .../... [new BR] and intended to be operated only on frequencies allocated by the Radio Regulations of the International Telecommunication Union for protected aeronautical use. As a consequence, Directive 2014/53/EU and, with respect to unmanned aircraft and their engines, propellers, parts and non-installed equipment which do not communicate with radio waves, Directive 2014/30/EU, apply to unmanned aircraft and their engines, propellers, parts and non-installed equipment in the ‘open’ category.

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<sup>(1)</sup> OJ reference to be added when the new ‘Basic Regulation’ repealing Regulation (EC) No 216/2008 will be adopted by the European Parliament and the Council. For referencing purposes, ‘Regulation (EU) .../... [new BR]’ is used in the proposed draft Regulation.

<sup>(2)</sup> Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62).

<sup>(3)</sup> Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast) (OJ L 96, 29.3.2014, p. 79).

- (3) Decision No 768/2008/EC of the European Parliament and of the Council <sup>(4)</sup> lays down common principles and reference provisions intended to apply across the legislation harmonising the conditions for the marketing of products in order to provide a coherent basis for revision or recasts of that legislation. In order to ensure consistency with other sectorial product legislation, this Regulation should therefore follow that Decision regarding the marketing of UAS intended to be operated in the ‘open’ category.
- (4) Regulation (EC) No 765/2008 of the European Parliament and of the Council <sup>(5)</sup> lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.
- (5) This Regulation applies to a UAS which is new to the Union market when it is placed on the market; that is to say it is either a new UAS made by a manufacturer established in the Union or a UAS, whether new or second-hand, imported from a third country.
- (6) This Regulation should apply to all forms of supply, including distance selling.
- (7) Special attention should be paid to ensure compliance of products in the context of an increase of e-commerce. To that end, Member States should be encouraged to pursue cooperation with the competent authorities in third countries and to develop cooperation between market surveillance authorities and customs. Market surveillance authorities should make use, when possible, of the ‘notice and action’ procedures and establish cooperation with their national authorities competent for the implementation of the Directive on electronic commerce <sup>(6)</sup>. They should establish close contacts allowing rapid response with key intermediaries that provide hosting services for products sold online.
- (8) Economic operators should be responsible for the compliance of UAS intended to be operated in the ‘open’ category with the requirements included in this Regulation, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as health and safety, and to guarantee fair competition on the Union market.
- (9) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they make available on the market UAS intended to be operated in the ‘open’ category which are in conformity with this Regulation. This Regulation should provide a clear and proportionate distribution of obligations

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<sup>(4)</sup> Decision No 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 Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

<sup>(5)</sup> 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 marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

<sup>(6)</sup> Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (‘Directive on electronic commerce’) (OJ L 178, 17.7.2000, p. 1).

which correspond to the role of each economic operator in the supply and distribution chain.

- (10) In order to facilitate communication between economic operators, national market surveillance authorities and consumers, Member States should encourage economic operators to include a website address in addition to the postal address.
- (11) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer.
- (12) It is necessary to ensure that UAS from third countries entering the Union market comply with the requirements of this Regulation when the UAS are intended to be operated in the 'open' category and, in particular, that appropriate conformity assessment procedures have been carried out by the manufacturers. Provision should therefore be made for importers to make sure that the UAS they place on the market comply with the requirements of this Regulation and that they do not place on the market UAS which do not comply with those requirements or which present a risk. Provision should also be made for importers to make sure that the conformity assessment procedures have been carried out and that the CE marking and technical documentation drawn up by the manufacturers is available for inspection by the competent national authorities.
- (13) The distributor makes a UAS intended to be operated in the 'open' category available on the market after it has been placed on the market by the manufacturer or the importer and the distributor must act with due care to ensure that its handling of the product does not adversely affect its compliance. Both importers and distributors are expected to act with due care in relation to the requirements applicable when placing or making products available on the market.
- (14) When placing on the market UAS intended to be operated in the 'open' category, every importer should indicate on the UAS his name, registered trade name or registered trademark and the address at which he can be contacted. Exceptions should be provided for in cases where the size or nature of the UAS does not allow this. This includes cases where the importer would have to open the packaging to put his name and address on the UAS.
- (15) Any economic operator that either places a UAS intended to be operated in the 'open' category on the market under his own name or trademark, or modifies a UAS intended to be operated in the 'open' category in such a way that compliance with the requirements of harmonisation legislation included in this Regulation may be affected, should be considered to be the manufacturer and should assume the obligations of the manufacturer.
- (16) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all the necessary information relating to the UAS concerned.

- (17) Ensuring the traceability of a UAS intended to be operated in the ‘open’ category throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates the market surveillance authorities’ task of tracing economic operators who make non-compliant UAS available on the market. When keeping the information required under this Regulation for the identification of other economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with a UAS or to whom they have supplied a UAS.
- (18) This Regulation should be limited to the expression of the essential requirements. In order to facilitate conformity assessment with those requirements, it is necessary to provide for a presumption of conformity for products which are in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council <sup>(7)</sup> for the purpose of expressing detailed technical specifications of those requirements.
- (19) The essential requirements should be worded precisely enough to create legally binding obligations. They should be formulated so as to make it possible to assess conformity with them even in the absence of harmonised standards or where the manufacturer chooses not to apply a harmonised standard. The degree of detail of the wording will depend on the characteristics of each sector.
- (20) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of the harmonisation legislation included in this Regulation.
- (21) In order to enable economic operators to demonstrate, and the competent authorities to ensure, that UAS intended to be operated in the ‘open’ category made available on the market conform to the essential requirements, it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectorial coherence and to avoid ad hoc variants, conformity assessment procedures should be chosen from among those modules.
- (22) Market surveillance authorities and UAS operators should have easy access to the EU declaration of conformity. In order to fulfil that requirement, manufacturers should ensure that each UAS intended to be operated in the ‘open’ category is accompanied either by a copy of the EU declaration of conformity or by the internet address at which the EU declaration of conformity can be accessed.

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<sup>(7)</sup> Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC 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 Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

- (23) To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts for UAS intended to be operated in the ‘open’ category should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, it should be possible for that single EU declaration of conformity to be a dossier made up of relevant individual declarations of conformity.
- (24) The CE marking, indicating the conformity of a product, is the visible consequence of a whole process comprising conformity assessment in a broad sense. The general principles governing the CE marking are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking on UAS intended to be operated in the ‘open’ category should be laid down in this Regulation.
- (25) In order to ensure compliance with the essential requirements laid down in this Regulation, it is necessary to lay down appropriate conformity assessment procedures to be followed by the manufacturer. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectorial coherence and to avoid ad hoc variants, conformity assessment procedures should be chosen from among those modules.
- (26) Conformity assessment procedures applicable to UAS intended to be operated in the ‘open’ category covered by this Regulation require the intervention of conformity assessment bodies, which are notified by the Member States to the Commission.
- (27) It is necessary to ensure a uniformly high level of performance of bodies performing conformity assessment of UAS intended to be operated in the ‘open’ category throughout the Union, and all such bodies should perform their functions at the same level and under conditions of fair competition. Therefore obligatory requirements should be set for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.
- (28) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in the harmonisation legislation included in this Regulation.
- (29) In order to ensure a consistent level of conformity assessment quality, it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.
- (30) The system set out in this Regulation should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.
- (31) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity, should be considered by the national public authorities throughout the Union as the means of demonstrating the technical competence of conformity assessment bodies.

- (32) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the appliances and the fittings to be placed on the Union market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies do in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified, and the monitoring of bodies already notified, also covers activities carried out by subcontractors and subsidiaries.
- (33) It is necessary to increase the efficiency and transparency of the notification procedure and, in particular, to adapt it to new technologies so as to enable online notification.
- (34) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.
- (35) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.
- (36) Interested parties should have the right to appeal against the result of a conformity assessment carried out by a notified body. For that reason, it is important to ensure that an appeal procedure against decisions taken by notified bodies is available.
- (37) Member States should take all appropriate measures to ensure that UAS covered by this Regulation may be placed on the market only if, when properly stored and used for its intended purpose or under conditions of use which can be reasonably foreseen, it does not endanger the health or safety of persons. UAS covered by this Regulation should be considered as non-compliant with the essential requirements laid down in this Regulation only under conditions of use which can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behaviour.
- (38) In order to ensure legal certainty, it is necessary to clarify that the rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to products falling within the scope of this Regulation. This Regulation should not prevent Member States from choosing the competent authorities to carry out those tasks. In order to ensure a smooth transition as regards the implementation of this Regulation, appropriate transitional measures should be provided.

- (39) UAS operators that have their principal place of business, or are established, or are resident in a third country and that are conducting UAS operations in, out or within the single European sky airspace should be subject to this regulation.
- (40) The measures provided for in this Regulation are based on Opinion No 01/2018 <sup>(8)</sup> issued by the European Aviation Safety Agency (EASA) in accordance with Article 65 of Regulation (EU) .../... [new BR],

HAS ADOPTED THIS REGULATION:

## SECTION 1

### *General provisions*

#### *Article 1. Subject matter and scope*

1. This Regulation lays down rules on the making available on the market and the free movement in the Union of those UAS intended to be operated under the rules and conditions of the ‘open’ category as defined in Regulation (EU) .../... [IR] <sup>(9)</sup>.
2. This Regulation lays down requirements for the design and manufacture of five classes of unmanned aircraft systems (UAS), as well as for UAS components, except for privately built UAS.
3. This Regulation lays down also rules for UAS operators that have their principal place of business, are established, or reside in a third country, when they conduct a UAS operation in the ‘open’ or ‘specific’ category within the single European sky airspace.

#### *Article 2. Definitions*

For the purposes of this Regulation, the following definitions apply:

1. ‘unmanned aircraft system (UAS) operator’ means any legal or natural person who operates or intends to operate one or more UAS;
2. ‘making available on the market’ means any supply of a product for distribution, consumption or use in the EU market in the course of a commercial activity, whether in exchange of payment or free of charge;
3. “‘open’ category’ means a category of UAS operation that, considering the risks involved, requires neither a prior authorisation by the competent authority, nor a declaration by the UAS operator before the operation takes place;

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<sup>(8)</sup> EASA Opinion No 01/2018 ‘Introduction of a regulatory framework for the operation of unmanned aircraft systems in the “open” and “specific” categories’ (RMT.0230), available at <https://www.easa.europa.eu/document-library/opinions>.

<sup>(9)</sup> OJ reference to be added when the draft Commission Regulation laying down rules and procedures for the operation of unmanned aircraft will be adopted. For referencing purposes, ‘Regulation (EU) .../... [IR]’ is used in the proposed draft Regulation.

4. 'unmanned aircraft system (UAS)' means the UA and the equipment to control the unmanned aircraft remotely;
5. 'product' means a UAS intended to be operated under the rules and conditions of the 'open' category or a UAS component as defined in Appendix 6;
6. 'Union harmonisation legislation' means any EU legislation harmonising the conditions for placing products on the market;
7. 'accreditation' means accreditation as defined in point 10 of Article 2 of Regulation (EC) No 765/2008;
8. 'conformity assessment' means the process demonstrating whether specified requirements relating to a product have been fulfilled;
9. 'CE marking' means a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixation;
10. 'manufacturer' means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark;
11. 'economic operators' means the manufacturer, the authorised representative of the manufacturer, the importer, and the distributor of the UAS;
12. 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market;
13. 'placing on the market' means the first making available of a UAS on the Union market;
14. 'harmonised standard' means a harmonised standard as defined in point (c) of point 1 of Article 2 of Regulation (EU) No 1025/2012;
15. 'technical specification' means a document that prescribes technical requirements to be fulfilled by a product, process or service;
16. 'single European sky airspace' means airspace above the territory to which the Treaties apply, as well as any other airspace where Member States apply Regulation (EU) No 551/2004 in accordance with Article 1(3) of that Regulation;
17. 'privately built UAS' means a UAS assembled or manufactured for the manufacturer's own use; this does not include UAS assembled from a set of parts placed on the market by the manufacturer as a single ready-to-assemble kit;
18. 'equipment to control unmanned aircraft remotely' means any instrument, equipment, mechanism, apparatus, appurtenance, software or accessory that is necessary for the safe operation of a UA other than a part and which is not carried on board that UAS;
19. 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in



- relation to specified tasks with regard to the latter's obligations under the relevant Union legislation;
20. 'market surveillance authority' means an authority of a Member State responsible for carrying out market surveillance on its territory;
  21. 'recall' means any measure aimed at achieving the return of a product that has already been made available to the end user;
  22. 'unmanned aircraft (UA)' means any aircraft operating or designed to operate autonomously or to be piloted remotely without a pilot on board;
  23. 'importer' means any natural or legal person established within the Union who places a product from a third country on the Union market;
  24. 'conformity assessment body' means a body that performs conformity assessment activities including calibration, testing, certification and inspection;
  25. 'withdrawal' means any measure aimed at preventing a product in the supply chain from being made available on the market;
  26. 'remote pilot' means a natural person responsible for safely conducting the flight of a UA by operating its flight controls, either manually or, when the UA flies automatically, by monitoring its course and remaining able to intervene and change its course at any time;
  27. 'follow-me mode' means a mode of operation of a UAS where the UA constantly follows a person or a device within a predetermined radius;
  28. 'electronic identification' means a system that transmits the identity of the UA so that it can be identified without direct physical access to that UA
  29. 'geo-awareness' means a function that can detect a potential breach of airspace limitations and provide the remote pilot with sufficient information and an appropriate alert to allow the remote pilot to take effective action to prevent that breach.

*Article 3.*        **Making available on the market**

Products that fall within the scope of this Regulation shall only be made available on the Union market if they comply with the requirements set out in Appendices 1 to 6.

*Article 4.*        **Free movement of products**

Member States shall not prohibit, restrict or impede, for the aspects covered by this Regulation, the making available on the market of products that fall within the scope of this Regulation and comply with this Regulation.

## SECTION 2

### *Obligations of economic operators*

#### *Article 5. Obligations of manufacturers*

1. When placing their product on the market, manufacturers shall ensure that it has been designed and manufactured in accordance with the requirements set out in Article 3.
2. Manufacturers shall draw up the technical documentation referred to in Article 16 and carry out the relevant conformity assessment procedure referred to in Article 12, or have it outsourced.

Where compliance of the product with the requirements in the relevant Appendices 1 to 6 has been demonstrated by that conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity referred to in Article 13 and affix the CE marking referred to in Article 14.

3. Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the product has been placed on the market.
4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Regulation. Changes in product design, characteristics or software, and changes in the harmonised standards or in technical specifications by reference to which conformity of a product is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by a product, manufacturers shall, to protect the health and safety of consumers, carry out sample testing of marketed products, investigate, and, if necessary, keep a register of complaints, of non-conforming products and product recalls, and shall keep distributors informed of any such monitoring.

5. Manufacturers shall ensure that procedures are in place to ensure that software upgrades that take place after placing the product on the market do not alter the compliance of the product.
6. Manufacturers shall ensure that their products bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging, or in a document accompanying it.
7. Manufacturers shall indicate their name, registered trade name or registered trademark and the postal address at which they can be contacted on the product or, where that is not possible, on its packaging, or in a document accompanying it. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be indicated in a language easily understood by end users and market surveillance authorities.

8. Manufacturers shall ensure that their products bear the UA class identification label defined in the related Appendices 1 to 5.
9. Manufacturers shall ensure that the product is accompanied by the instructions and information required by Appendices 1 to 6 in a language which can be easily understood by consumers and other end users, as determined by the Member State concerned. Such instructions and information, as well as any labelling, shall be clear, understandable and legible.
10. Manufacturers shall ensure that each product is accompanied by a copy of the EU declaration of conformity or by a simplified EU declaration of conformity. Where a simplified EU declaration of conformity is provided, it shall contain the exact internet address where the full text of the EU declaration of conformity can be obtained.
11. Manufacturers who consider or have reason to believe that products which they have placed on the market are not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that product into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the product presents a risk, manufacturers shall immediately inform the market surveillance authorities of the Member States in which they made the product available on the market to that effect, giving details, in particular, of the non-compliance, of any corrective measures taken and of the results thereof.
12. Manufacturers shall, further to a reasoned request from a competent market surveillance or authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the product with this Regulation, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by the product which they have placed on the market.

#### *Article 6.*            **Authorised representatives**

1. A manufacturer may, by a written mandate, appoint an authorised representative.
2. The obligations laid down in Article 5(1) and the obligation to draw up technical documentation laid down in Article 5(2) shall not form part of the authorised representative's mandate.
3. An 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:
  - (a) keep the EU declaration of conformity and the technical documentation at the disposal of national market surveillance authorities for 10 years after the product has been placed on the market;
  - (b) further to a reasoned request from a market surveillance or border control authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the product;

- (c) cooperate with the market surveillance or border control authorities, at their request, on any action taken to eliminate the non-conformity of the products covered by the authorised representative's mandate or the safety risks posed by it.

#### *Article 7.*      **Obligations of importers**

1. Importers shall only place products compliant with the requirements set out in this Regulation on the Union market.
2. Before placing a product on the market, importers shall ensure that:
  - (a) the appropriate conformity assessment procedure referred to in Article 12 has been carried out by the manufacturer;
  - (b) the manufacturer has drawn up the technical documentation referred to in Article 16;
  - (c) the product bears the CE marking and, when required, the UA class identification label;
  - (d) the product is accompanied by the documents referred to in Article 5(9) and (10);
  - (e) the manufacturer has complied with the requirements set out in Article 5(6) and (7).

Where an importer considers or has reason to believe that a product is not in conformity with the requirements set out in Article 3, he shall not place the product on the market until it has been brought into conformity. Furthermore, where the product presents a risk, the importer shall inform the manufacturer and the competent market surveillance authorities to that effect.

3. Importers shall indicate on the product their name, registered trade name or registered trademark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the product. The contact details shall be in a language easily understood by end users and market surveillance authorities.
4. Importers shall ensure that the product is accompanied by the instructions and information required by Appendices 1 to 6 in a language which can be easily understood by consumers and other end users, as determined by the Member State concerned. Such instructions and information, as well as any labelling, shall be clear, understandable and legible.
5. Importers shall ensure that, while the product is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the requirements set out in Article 3.
6. When deemed appropriate with regard to the risks presented by a product, importers shall, to protect the health and safety of end users and third parties, carry out sample

testing of products made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming of products and product system recalls, and shall keep distributors informed of any such monitoring.

7. Importers who consider or have reason to believe that a product which they have placed on the market is not in conformity with the applicable Union harmonisation legislation shall immediately take the corrective measures necessary to bring that product into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the product presents a risk, importers shall immediately inform the market surveillance authorities of the Member States in which they made the product available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.
8. Importers shall, for 10 years after the product has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.
9. Importers shall, further to a reasoned request from the competent market surveillance authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the product in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by the product which they have placed on the market.

#### *Article 8.*            **Obligations of distributors**

1. When making a product available on the market, distributors shall act with due care in relation to the requirements of this Regulation.
2. Before making a product available on the market, distributors shall verify that the product bears the CE marking and, when relevant, the class identification label, is accompanied by the documents referred to in Article 5(9) and (10), and that the manufacturer and the importer have complied with the requirements set out in Article 5(6) and (7) and Article 7(3).

Distributors shall ensure that the product is accompanied by the instructions and information required by Appendices 1 to 6 in a language which can be easily understood by consumers and other end users, as determined by the Member State concerned. Such instructions and information, as well as any labelling, shall be clear, understandable and legible.

Where a distributor considers or has reason to believe that a product is not in conformity with the requirements set out in Article 3, he shall not make the product available on the market until it has been brought into conformity. Furthermore, where the product presents a risk, the distributor shall inform the manufacturer or the importer to that effect, as well as the competent market surveillance authorities.

3. Distributors shall ensure that, while a product is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the requirements set out in Article 3.
4. Distributors who consider or have reason to believe that a product which they have made available on the market is not in conformity with the applicable Union harmonisation legislation shall make sure that the corrective measures necessary to bring that product into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the product presents a risk, distributors shall immediately inform the market surveillance authorities of the Member States in which they made the product available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.
5. Distributors shall, further to a reasoned request from the competent market surveillance authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the product. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by the product which they have made available on the market.

*Article 9.*            **Cases in which obligations of manufacturers apply to importers and distributors**

An importer or distributor shall be considered a manufacturer for the purposes of this Regulation, and shall be subject to the obligations of the manufacturer under Article 5, where he places a product on the market under his name or trademark or modifies the product already placed on the market in such a way that compliance with this Regulation may be affected.

*Article 10.*           **Identification of economic operators**

Economic operators shall, on request, identify the following to the market surveillance authorities:

1. any economic operator who has supplied them with a product;
2. any economic operator to whom they have supplied a product.

Economic operators shall be able to present the information referred to in the first paragraph for 10 years after they have been supplied with the product and for 10 years after they have supplied the product.

## SECTION 3

### *Conformity of the product*

#### *Article 11.*      **Presumption of conformity**

A product which is in conformity with harmonised standards or parts thereof, the references of which have been published in the *Official Journal of the European Union*, shall be presumed to be in conformity with the requirements covered by those standards or parts thereof set out in Appendices 1 to 6.

#### *Article 12.*      **Conformity assessment procedures**

1. The manufacturer shall perform a conformity assessment of the product using one of the procedures provided in the following section with a view to establishing its compliance with the requirements set out in one of the Appendices 1 to 6. The conformity assessment shall take into account all intended and foreseeable operating conditions.
2. The procedures available to conduct the conformity assessment are the following:
  - (a) internal production control set out in Appendix 7:
    - (i) when assessing the compliance of a toy in the meaning of Directive 2009/48/EC <sup>(10)</sup> with the requirements set out in Appendix 1;
    - (ii) when assessing the compliance of a product with the requirements set out in Appendix 5;
    - (iii) where, in assessing the compliance of a product with the requirements set out in Appendices 1, 2 or 6, the manufacturer has applied harmonised standards, the references of which have been published in the *Official Journal of the European Union*, for all the requirements for which such standards exist;
  - (b) EU-type examination followed by conformity to type based on internal production control set out in Appendix 8;
  - (c) conformity based on full quality assurance set out in Appendix 9.

#### *Article 13.*      **EU declaration of conformity**

1. The EU declaration of conformity referred to in Article 5(10) shall, when relevant, identify the class of the UA and state that compliance with the corresponding requirements set out in Appendices 1 to 5 has been demonstrated.
2. The EU declaration of conformity shall have the model structure set out in Appendix 11, shall contain the elements set out in that Appendix, and shall be

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<sup>(10)</sup> Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1).

continuously updated. It shall be translated into the language or languages required by the Member State in which market the product is placed or made available.

3. The simplified EU declaration of conformity referred to in Article 5(10) shall contain the elements set out in Appendix 12 and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the product is placed or made available on the market. The full text of the EU declaration of conformity shall be available at the internet address referred to in the simplified EU declaration of conformity, in a language or languages required by the Member State in which the product is placed or made available on the market.
4. Where a product is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned, including their publication references.
5. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the product with the requirements laid down in this Regulation.

*Article 14.*            **General principles of the CE marking**

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

*Article 15.*    **Rules and conditions for affixing the CE marking, the UAS class identification label and the identification number of the notified body**

1. The CE marking and, when relevant, the UA class identification label, shall be affixed visibly, legibly and indelibly to the product, unless that is not possible or not warranted on account of the nature of the product. The CE marking and the UA class identification label shall also be affixed visibly and legibly to the packaging and to the user's manual.

The UA class identification label shall be affixed on the right side of the CE marking and have a similar size.

2. The CE marking and the UA class identification label shall be affixed before the product is placed on the market.
3. The CE marking and the UA class identification label shall be followed by the identification number of the notified body where the conformity assessment procedure set out in Appendix 9 is applied.

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



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

*Article 16.*      **Technical documentation**

1. The technical documentation shall contain all relevant data or details of the means used by the manufacturer to ensure that the product complies with the related requirements set out in Appendices 1 to 6. It shall, at least, contain the elements set out in Appendix 10.
2. The technical documentation shall be drawn up before the product is placed on the market and shall be continuously updated.
3. The technical documentation and correspondence relating to any EU-type examination procedure shall be drawn up in an official language of the Member State in which the notified body is established or in a language acceptable to that body.
4. Where the technical documentation does not comply with paragraphs 1, 2 or 3 of this Article, and in doing so fails to present sufficient relevant data or means used to ensure compliance of the product with the related requirements set out in Appendices 1 to 6, the market surveillance authority may ask the manufacturer or the importer to have a test performed by a body acceptable to the market surveillance authority at the expense of the manufacturer or the importer within a specified period in order to verify compliance with the related requirements set out in Appendices 1 to 6.

## SECTION 4

### *Notification of conformity assessment bodies*

#### *Article 17.*      **Notification**

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this Regulation.

#### *Article 18.*      **Notifying authorities**

1. Member States shall designate a notifying authority that 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 23.
2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of, and in accordance with, Regulation (EC) No 765/2008.
3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article 19. In addition, it shall have arrangements to cover liabilities arising out of its activities.
4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

#### *Article 19.*      **Requirements relating to notifying authorities**

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.
2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.
3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.
4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.
5. A notifying authority shall safeguard the confidentiality of the information it obtains.
6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

*Article 20.*            **Information obligation on notifying authorities**

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

*Article 21.*            **Requirements relating to notified bodies**

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.
2. A conformity assessment body shall be established under national law of a Member State and have legal personality.
3. A conformity assessment body shall be a third-party body independent of the organisation it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of the product which it assesses may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4. A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the product which they assess, nor the representative of any of those parties. This shall not preclude the use of assessed product that is necessary for the operations of the conformity assessment body or the use of such product for personal purposes.

A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of that product, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall, in particular, apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, 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.

6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Appendix 8 or 9 in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of product in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

- (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
- (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures; it shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;
- (c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product in question and the mass or serial nature of the production process.

A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7. The personnel responsible for carrying out conformity assessment tasks shall have the following:
  - (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
  - (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
  - (c) appropriate knowledge and understanding of the essential requirements, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation;
  - (d) the ability to draw up EU-type examination certificates or quality system approvals, records and reports demonstrating that assessments have been carried out.
8. The impartiality of the conformity assessment bodies, their top-level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

The remuneration of the top-level management and of the personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall

not depend on the number of assessments carried out or on the results of those assessments.

9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the Member State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.
10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Appendices 8 and 9 or any provision of national law giving effect to them, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.
11. Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities, the regulatory activities in the area of UAS and frequency planning, and the activities of the notified body coordination group established under the relevant Union harmonisation legislation, and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

#### *Article 22.*        **Presumption of conformity of notified bodies**

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof, the references of which have been published in the *Official Journal of the European Union*, it shall be presumed to comply with the requirements set out in Article 21 in so far as the applicable harmonised standards cover those requirements.

#### *Article 23.*        **Subsidiaries of and subcontracting by notified bodies**

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 21 and shall inform the notifying authority accordingly.
2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries, wherever these are established.
3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.
4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Appendices 8 and 9.

*Article 24.*      **Application for notification**

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.
2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules, and the product for which that body claims to be competent, as well as by an accreditation certificate issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 21.

*Article 25.*      **Notification procedure**

1. Notifying authorities may only notify conformity assessment bodies which have satisfied the requirements laid down in Article 21.
2. They shall notify conformity assessment bodies to the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.
3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules, and the product concerned and the relevant accreditation certification.
4. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within 2 weeks of a notification.  
  
Only such a body shall be considered a notified body for the purposes of this Regulation.
5. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.

*Article 26.*      **Identification numbers and lists of notified bodies**

1. The Commission shall assign an identification number to a notified body.  
It shall assign a single such number even where the body is notified under several Union acts.
2. The Commission shall make publicly available the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified.

The Commission shall ensure that the list is kept up to date.

*Article 27.*      **Changes to notifications**

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 21, or that it fails to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw the notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.
2. In the event of restriction, suspension or withdrawal of the notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

*Article 28.*      **Challenge of the competence of notified bodies**

1. The Commission shall investigate all cases where it has doubts, or doubt is brought to its attention, about the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.
2. The notifying Member State shall provide the Commission, on request, with all the information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.
3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.
4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including de-notification if necessary.

*Article 29.*      **Operational obligations of notified bodies**

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided in Appendices 8 and 9.
2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the UA or UAS technology in question, and the mass or serial nature of the production process.  
  
In doing so, they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the UA or UAS with this Regulation.
3. Where a notified body finds that the requirements set out in Appendices 1 to 6 or in corresponding harmonised standards or other technical specifications have not been

met by a manufacturer, it shall require the manufacturer to take appropriate corrective measures and shall not issue an EU-type examination certificate or a quality system approval.

4. Where, in the course of the monitoring of conformity following the issue of an EU-type examination certificate or a quality system approval, a notified body finds that a product no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the EU-type examination certificate or the quality system approval if necessary.
5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any EU-type examination certificates or quality system approvals, as appropriate.

*Article 30.*            **Appeal against decisions of notified bodies**

Member States shall ensure that an appeal procedure against decisions of the notified bodies is available.

*Article 31.*            **Information obligation on notified bodies**

1. Notified bodies shall inform the notifying authority of the following:
  - (a) any refusal, restriction, suspension or withdrawal of an EU-type examination certificate or a quality system approval in accordance with the requirements of Appendices 8 and 9;
  - (b) any circumstances affecting the scope of, or conditions for, notification;
  - (c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;
  - (d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.
2. Notified bodies shall, in accordance with the requirements of Appendices 8 and 9, provide the other bodies notified under this Regulation carrying out similar conformity assessment activities covering the same categories of UA or UAS with the relevant information on issues relating to negative and, on request, positive conformity assessment results.
3. Notified bodies shall fulfil information obligations under Appendices 8 and 9.

*Article 32.*            **Exchange of experience**

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.



*Article 33.*      **Coordination of notified bodies**

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Regulation are put in place and properly operated in the form of a sectorial group of notified bodies.

Member States shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives.

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## **SECTION 5**

### ***Union market surveillance, control of products entering the Union market and Union safeguard procedure***

#### **Article 34. Market surveillance and control of products entering the Union market**

1. Member States shall organise and perform surveillance of the products that fall within the scope of this Regulation and are placed on the Union market in accordance with Article 15(3) and Articles 16 to 26 of Regulation (EU) No 765/2008.
2. Member States shall organise and perform control of the products that fall within the scope of this Regulation and enter the Union market in accordance with Articles 15(5) and Articles 27 to 29 of Regulation (EU) No 765/2008.
3. Member States shall ensure that their market surveillance and border control authorities cooperate with the competent authorities designated under Article 8 of Regulation (EU) .../... [IR] on safety matters and shall establish appropriate communication and coordination mechanisms between them, making the best use of the information contained in the occurrence reporting system defined under Regulation (EU) No 376/2014 <sup>(1)</sup> and the information systems defined in Articles 22 and 23 of Regulation (EC) No 765/2008.

#### **Article 35. Procedure for dealing with products presenting a risk at national level**

1. Where the market surveillance authorities of one Member State have sufficient reason to believe that a product presents a risk to the health or safety of persons or to other aspects of public interest protection covered by this Regulation, they shall carry out an evaluation in relation to the product concerned, covering all applicable requirements laid down in this Regulation. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.

Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the product does not comply with the requirements laid down in this Regulation, they shall, without delay, require the relevant economic operator to take all appropriate corrective actions to bring the product into compliance with those requirements, to withdraw the product from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

The market surveillance authorities shall inform the relevant notified body accordingly.

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<sup>(1)</sup> Regulation (EU) No 376/2014 of the European Parliament and of the Council of 3 April 2014 on the reporting, analysis and follow-up of occurrences in civil aviation, amending Regulation (EU) No 996/2010 of the European Parliament and of the Council and repealing Directive 2003/42/EC of the European Parliament and of the Council and Commission Regulations (EC) No 1321/2007 and (EC) No 1330/2007 (OJ L 122, 24.4.2014, p. 18).

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this paragraph.

2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.
3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all products concerned that it has made available on the market throughout the Union.
4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the product being made available on their national market, to withdraw the product from that market or to recall it.

The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.

5. The information referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant product, the origin of the product, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:
  - (a) failure of the product to meet the requirements set out in Article 3; or
  - (b) shortcomings in the harmonised standards referred to in Article 11 conferring a presumption of conformity.
6. Member States other than the Member State initiating the procedure under this Article shall, without delay, inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the product concerned, and, in the event of disagreement with the adopted national measure, of their objections.
7. Where, within 3 months of receipt of the information referred to in paragraph 5, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.
8. Member States shall ensure that appropriate restrictive measures, such as withdrawal of the product from the market, are taken in respect of the product concerned without delay.

*Article 36.*      **Union safeguard procedure**

1. Where, on completion of the procedure set out in Article 35(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant product is withdrawn or recalled from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.
3. Where the national measure is considered justified and the non-compliance of the product is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 35(5) of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

*Article 37.*      **Compliant product which presents a risk**

1. Where, having carried out an evaluation under Article 35(1), a Member State finds that although the product is in compliance with this Regulation, it presents a risk to the health or safety of persons or to other aspects of public interest protection covered by this Regulation, it shall require the relevant economic operator to take all appropriate measures to ensure that the product concerned, when placed on the market, no longer presents that risk, to withdraw the product from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.
2. The economic operator shall ensure that corrective action is taken in respect of all the products concerned that he has made available on the market throughout the Union.
3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the product concerned, the origin and the supply chain of product, the nature of the risk involved and the nature and duration of the national measures taken.
4. The Commission shall, without delay, enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not and, where necessary, propose appropriate measures.

5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

*Article 38.*      **Formal non-compliance**

1. Without prejudice to Article 35, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:
  - (a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 14 or Article 15 of this Regulation;
  - (b) the CE marking has not been affixed;
  - (c) the identification number of the notified body, where the conformity assessment procedure set out in Appendix 9 is applied, has been affixed in violation of Article 17 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) technical documentation is either not available or not complete;
2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the product being made available on the market or ensure that it is withdrawn or recalled from the market.

## **SECTION 6**

### ***Third-country UAS operators***

#### **Article 39. Third-country UAS operators**

1. UAS operators that have their principal place of business, are established, or reside in a third country, shall comply with Regulation (EU) .../... [IR] for the purpose of UAS operations within the single European sky airspace.
2. The competent authority for the third-country UAS operator is the competent authority of the EU Member State where the UAS operator intends to operate.
3. By way of derogation from paragraph 1 of this Article, a certificate of the remote pilot competency or the UAS operator, or an equivalent document, may be recognised by the competent authority for the purpose of operation within, to, and out of the EU provided that:
  - (a) the third country asked for such recognition;
  - (b) the certificate of the remote pilot competency or the UAS operator's certificate are valid documents of the State of issue; and
  - (c) EASA has ensured that the requirements on the basis of which such certificates have been issued provide the same level of safety as this Regulation does.

## **SECTION 7**

### ***Final and transitional provisions***

#### ***Article 40. Penalties***

Member States shall provide for penalties applicable to infringements by economic operators of the provisions of this Regulation and shall take all measures necessary to ensure that they are enforced.

The penalties provided for shall be effective, proportionate and dissuasive. They may include criminal penalties for serious infringements. Member States shall notify those rules to the Commission by DD/MM/YY, and shall notify it without delay of any subsequent amendment affecting them.

#### ***Article 41. Technical guidelines***

In order to facilitate the implementation of this Regulation, the Commission shall draw up non-binding guidelines in consultation with the stakeholders.

#### ***Article 42. Entry into force and application***

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

It shall apply from ... [2 years after the date of entry into force].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission*  
*The President*  
*[...]*

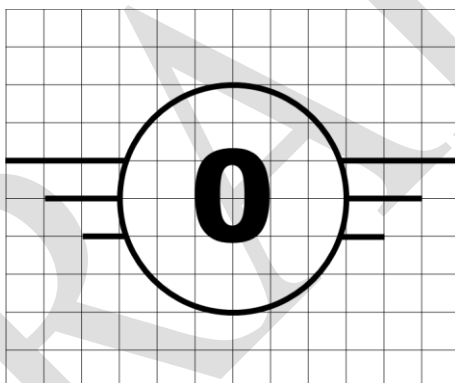
## APPENDICES

### *Appendix 1*

#### ***Product requirements for a class C0 UAS***

A class C0 UAS shall:

1. have an MTOM, including payload, of less than 250 g;
2. be safely controllable by a remote pilot following the manufacturer's instructions;
3. if equipped with a follow-me mode, when this function is on, keep a distance not exceeding 50 m from the remote pilot, and allow the remote pilot to regain control of the UA or to activate an emergency procedure that terminates the flight;
4. be placed on the market with clear operational instructions and warnings highlighting the risks related to UAS operations, which shall be adapted to the age of the user;
5. include an information notice defined by the European Aviation Safety Agency (EASA) providing applicable limitations and obligations, in accordance with Regulation (EU) .../... [IR]; and
6. bear the following class identification label on the UA in a visible manner:



7. be designed and manufactured in such a way as to fly safely;
8. have a maximum speed in level flight of 19 m/s;
9. have a maximum attainable height above the take-off point limited to 120 m or be equipped with a system that limits the height above the surface or above the take-off point to 120 m;
10. be designed and constructed in such a way as to minimise injury to persons during operation; sharp edges shall be avoided; if equipped with propellers, the UAS shall be designed in such a way as to limit any injury that may be inflicted by the propeller blades;
11. if powered by electricity, the nominal voltage shall not exceed 24 V direct current (DC) or the equivalent alternating current (AC) voltage; its accessible parts shall not exceed 24 V DC or the equivalent AC voltage; internal voltages shall not exceed 24 V DC or the equivalent AC voltage unless it is ensured that the voltage and current



combination generated does not lead to any risk or harmful electric shock even when the UAS is damaged.

Requirements 7 to 11 do not apply to UAS that are already compliant with the requirements defined in Directive 2009/48/EC on the safety of toys.

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## Appendix 2

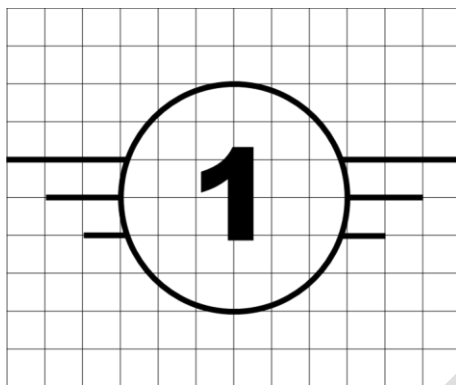
### *Product requirements for a class C1 UAS*

A class C1 UAS shall:

1. be made of materials and have performance and physical characteristics such as to ensure that in the event of an impact at terminal velocity with a human head, the energy transmitted to the human head is less than 80 J, or, as an alternative, the UAS shall have an MTOM, including payload, of less than 900 g;
2. have a maximum speed in level flight of 19 m/s;
3. have a maximum attainable height above the take-off point limited to 120 m or be equipped with a system that limits the height above the surface or above the take-off point to a value selectable by the remote pilot; in the latter case, clear information about the height of the UA above the surface or take-off point during flight shall be provided to the remote pilot;
4. be designed and manufactured in such a way as to fly safely;
5. be safely controllable by a pilot following the manufacturer's instructions;
6. have the requisite mechanical strength and, where appropriate, stability to withstand any stress to which it is subjected during use without any breakage or deformation that might interfere with its safe flight;
7. be designed and constructed in such a way as to minimise injury to persons or damage to property during operation; sharp edges shall be avoided; if equipped with propellers, they shall be designed in such a way as to limit any injury that may be inflicted by the propeller blades;
8. in case of a loss of data link, have a reliable and predictable method for the UA to recover or terminate the flight in a way that reduces the effect on third parties in the air or on the ground;
9. have a sound pressure level not exceeding 60 dB(A) (measured at a 3-m distance from the UA);
10. if powered by electricity, the nominal voltage shall not exceed 24 V DC or the equivalent AC voltage; its accessible parts shall not exceed 24 V DC or the equivalent AC voltage; internal voltages shall not exceed 24 V DC or the equivalent AC voltage unless it is ensured that the voltage and current combination generated does not lead to any risk or harmful electric shock even when the UAS is damaged;
11. have an electronic identification system that shall:
  - (a) allow the user to insert the 10-digit UAS operator registration number;
  - (b) provide in real time during the whole duration of the flight the following information through electronic data:
    - (i) UAS operator registration number;
    - (ii) the unique serial number of the UA or the add-on;

- (iii) geographical position of the UA, its height and associated time; and
    - (iv) geographical position of the UA take-off point;
  - (c) the information shall be protected against unauthorised modification;
12. be equipped with a geo-awareness system that provides:
- (a) an interface to load and update data containing information on airspace limitations, as defined by Regulation (EU) .../... [IR], which ensures that the process of loading or updating of such data does not degrade its integrity and validity;
  - (b) a warning alert when a potential breach of airspace limitations is detected; and
  - (c) information on its status as well as a warning alert when the positioning or navigation of the UA cannot ensure the proper functioning of the system;
13. if the UA has a function that limits its access to certain airspace areas or volumes, this function shall operate in such a manner that it interacts smoothly with the flight control system of the UA without adversely affecting flight safety; in addition, clear information shall be provided to the remote pilot when the UA flight control system is automatically engaged to keep the UA out of these areas;
14. provide the remote pilot with clear warning when the battery of the UA or its control station reaches a low level such that the remote pilot has sufficient time to safely land the UA;
15. be equipped with lights that cannot be confused with the navigation lights of a manned aircraft as required for controllability:
- (a) in daylight conditions;
  - (b) during night, if designed for night operation;
16. if equipped with a follow-me mode, when this function is on, keep a distance not exceeding 50 m from the remote pilot, and allow the remote pilot to regain control of the UA or to activate an emergency procedure that terminates the flight;
17. have a unique serial number that must be affixed in a legible manner on the UA and the packaging or the user's manual;
18. be placed on the market with a user's manual providing the characteristics of the UA (including but not limited to the mass of the UA, its MTOM, including its payload, the frequency of the electronic identification emission, the general characteristics of allowed payloads in terms of mass and dimensions, a description of the behaviour of the UA in case of a loss of data link), clear operational instructions, troubleshooting procedures and operational limitations (including but not limited to meteorological conditions and day/night operations) as well as an appropriate description of all the risks related to UAS operations;
19. include an information notice defined by EASA providing applicable limitations and obligations in accordance with Regulation (EU) .../... [IR];

20. bear the following label on the UA in a visible manner:



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### Appendix 3

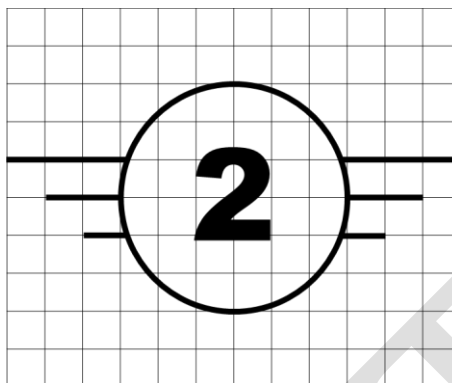
#### *Product requirements for a class C2 UAS*

A class C2 UAS shall:

1. have an MTOM, including payload, of less than 4 kg;
2. have a maximum attainable height above the take-off point limited to 120 m or be equipped with a system that limits the height above the surface or above the take-off point to a value selectable by the remote pilot; in the latter case, clear information about the height of the UA above the surface or take-off point during flight shall be provided to the remote pilot;
3. be designed and manufactured in such a way as to fly safely;
4. be safely controllable by a pilot following the manufacturer's instructions;
5. have the requisite mechanical strength and, where appropriate, stability to withstand any stress to which it is subjected during use without any breakage or deformation that might interfere with its safe flight;
6. in the case of a tethered UA, the tensile length of the tether shall be less than 50 m and its mechanical strength shall be no less than:
  - (a) for heavier-than-air aircraft, 10 times the weight of the aerodyne at maximum mass;
  - (b) for lighter-than-air aircraft, 4 times the force exerted by the combination of the maximum static thrust and the aerodynamic force of the maximum allowed wind speed in flight;
7. be designed and constructed in such a way as to minimise injury to persons or damage to property during operation; sharp edges shall be avoided; if equipped with propellers, they shall be designed in such a way as to limit any injury that may be inflicted by the propeller blades;
8. unless tethered, in case of a loss of data link, have a reliable and predictable method for the UA to recover or terminate the flight in a way that reduces the effect on third parties in the air or on the ground;
9. unless tethered, be equipped with a remote pilot data link protected against unauthorised access to the command and control functions;
10. unless it is a fixed-wing UA, be equipped with a low-speed mode selectable by the remote pilot and limiting the maximum cruising speed to no more than 3 m/s.
11. have a sound pressure level not exceeding 60 dB(A) (measured at a 3-m distance from the UA);
12. if powered by electricity, the nominal voltage shall not exceed 48 V DC or the equivalent AC voltage; its accessible parts shall not exceed 48 V DC or the equivalent AC voltage; internal voltages shall not exceed 48 V DC or the equivalent AC voltage unless it is ensured that the voltage and current combination generated does not lead to any risk or harmful electric shock even when the UAS is damaged;

13. unless tethered, have an electronic identification system that shall:
  - (a) allow the user to insert the 10-digit UAS operator registration number;
  - (b) provide in real time during the whole duration of the flight the following information through electronic data:
    - (i) UAS operator registration number;
    - (ii) the unique serial number of the UA or the add-on;
    - (iii) geographical position of the UA, its height and associated time; and
    - (iv) geographical position of the UA take-off point;
  - (c) the information shall be protected against unauthorised modification;
14. be equipped with a geo-awareness system providing:
  - (a) an interface to load and update data containing information on airspace limitations, as defined by Regulation (EU) .../... [IR], which ensures that the process of loading or updating of such data does not degrade its integrity and validity;
  - (b) a warning alert when a potential breach of airspace limitations is detected; and
  - (c) information on its status as well as a warning alert when the positioning or navigation of the UA cannot ensure the proper functioning of the system;
15. if the UA has a function that limits its access to certain airspace areas or volumes, this function shall operate in such a manner that it interacts smoothly with the flight control system of the UA without adversely affecting flight safety; in addition, clear information shall be provided to the remote pilot when the UA flight control system is automatically engaged to keep the UA out of these areas;
16. provide the remote pilot with clear warning when the battery of the UA or its control station reaches a low level such that the remote pilot has sufficient time to safely land the UA;
17. be equipped with lights for the purpose of controllability or visibility of the UA; the design of the lights shall not be confused with the navigation lights of manned aircraft;
18. have a unique serial number that must be affixed in a legible manner on the packaging, the user's manual or the UA;
19. be placed on the market with a user's manual providing the characteristics of the UA (including but not limited to the mass of the UA, its MTOM, including its payload, the frequency of the electronic identification emission, the general characteristics of allowed payloads in terms of mass and dimensions, a description of the behaviour of the UA in case of a loss of data link), clear operational instructions, troubleshooting procedures, and operational limitations (including but not limited to meteorological conditions and day/night operations) as well as an appropriate description of all the risks related to UAS operations;

20. include an information notice defined by EASA providing applicable limitations and obligations in accordance with Regulation (EU) .../... [IR]; and
21. bear the following label on the UA in a visible manner:



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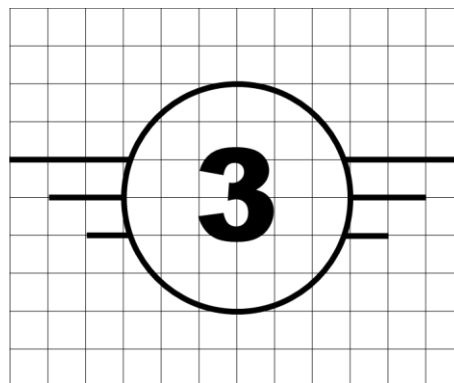
*Product requirements for a class C3 UAS*

A class C3 UAS shall:

1. have an MTOM, including payload, of less than 25 kg;
2. have a maximum attainable height above the take-off point limited to 120 m or be equipped with a system that limits the height above the surface or above the take-off point to a value selectable by the remote pilot; in the latter case, clear information about the height of the UA above the surface or take-off point during flight shall be provided to the remote pilot;
3. be designed and manufactured in such a way as to fly safely;
4. be safely controllable by a pilot following the manufacturer's instructions;
5. in the case of a tethered UA, the tensile length of the tether shall be less than 50 m and its mechanical strength shall be no less than:
  - (a) for heavier-than-air aircraft, 10 times the weight of the aerodyne at maximum mass;
  - (b) for lighter-than-air aircraft, 4 times the force exerted by the combination of the maximum static thrust and the aerodynamic force of the maximum allowed wind speed in flight;
6. unless tethered, in case of a loss of data link, have a reliable and predictable method for the UA to recover or terminate the flight in a way that reduces the effect on third parties in the air or on the ground;
7. if powered by electricity, the nominal voltage shall not exceed 48 V DC or the equivalent AC voltage; its accessible parts shall not exceed 48 V DC or the equivalent AC voltage; internal voltages shall not exceed 48 V DC or the equivalent AC voltage unless it is ensured that the voltage and current combination generated does not lead to any risk or harmful electric shock even when the UAS is damaged;
8. unless tethered, have an electronic identification system that shall:
  - (a) allow the user to insert the 10-digit UAS operator registration number;
  - (b) provide in real time during the whole duration of the flight the following information through electronic data:
    - (i) UAS operator registration number;
    - (ii) the unique serial number of the UA or the add-on;
    - (iii) geographical position of the UA, its height and associated time; and
    - (iv) geographical position of the UA take-off point;
  - (c) the information shall be protected against unauthorised modification;
9. be equipped with a geo-awareness system providing:



- (a) an interface to load and update data containing information on airspace limitations, as defined by Regulation (EU) .../... [IR], which ensures that the process of loading or updating of such data does not degrade its integrity and validity;
  - (b) a warning alert when a potential breach of airspace limitations is detected; and
  - (c) information on its status as well as a warning alert when the positioning or navigation of the UA cannot ensure the proper functioning of the system;
10. if the UA has a function that limits its access to certain airspace areas or volumes, this function shall operate in such a manner that it interacts smoothly with the flight control system of the UA without adversely affecting flight safety; in addition, clear information shall be provided to the remote pilot when the UA flight control system is automatically engaged to keep the UA out of these areas;
  11. provide the remote pilot with clear warning when the battery of the UA or its control station reaches a low level such that the remote pilot has sufficient time to safely land the UA;
  12. be equipped with lights for the purpose of controllability or visibility of the UA; the design of the lights shall not be confused with the navigation lights of a manned aircraft;
  13. have a unique serial number that must be affixed in a legible manner on the packaging, the user's manual or the UA;
  14. be placed on the market with a user's manual providing the characteristics of the UA (including but not limited to the mass of the UA, the MTOM, including its payload, the frequency of the electronic identification emission, the general characteristics of allowed payloads in terms of mass and dimensions, a description of the behaviour of the UA in case of a loss of data link), clear operational instructions, troubleshooting procedures, and operational limitations (including but not limited to meteorological conditions and day/night operations) as well as an appropriate description of all the risks related to UAS operations;
  15. include an information notice defined by EASA providing applicable limitations and obligations in accordance with Regulation (EU) .../... [IR]; and
  16. bear the following label on the UA in a visible manner:

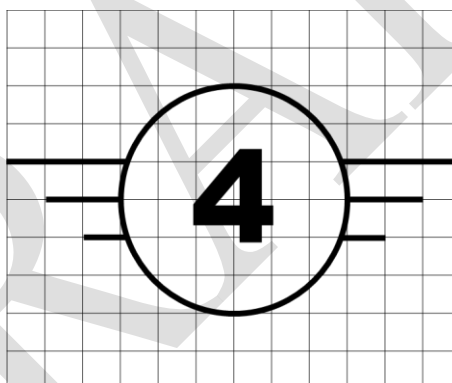


*Appendix 5*

***Product requirements for a class C4 UAS***

A class C4 UAS shall:

1. have an MTOM, including payload, of less than 25 kg;
2. be designed and manufactured in such a way as to fly safely;
3. not be capable of automatic control modes;
4. be placed on the market with a user's manual providing the characteristics of the UA (including but not limited to the mass of the UA and its MTOM, including its payload, and a description of the behaviour of the UA in case of a loss of data link), clear operational instructions and operational limitations (including but not limited to meteorological conditions and day/night operations) as well as an appropriate description of all the risks related to UAS operations;
5. include an information notice defined by EASA providing applicable limitations and obligations in accordance with Regulation (EU) .../... [IR]; and
6. bear the following label on the UA in a visible manner:



*Appendix 6*

***Electronic identification system***

An electronic identification add-on shall:

1. allow the user to insert the 10-digit UAS operator registration number;
2. provide in real time during the whole duration of the flight the following information through electronic data:
  - (a) the UAS operator registration number;
  - (b) the unique serial number of the add-on;
  - (c) the geographical position of the UA, its height and associated time; and
  - (d) the geographical position of the UA take-off point;
3. the information shall be protected against unauthorised modification.

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**Conformity assessment Module A — Internal production control  
as per Annex II to Decision No 768/2008/EC**

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4 of this Appendix, and ensures and declares on his sole responsibility that the products concerned satisfy the applicable requirements set out in Appendices 1 to 6.
2. **Technical documentation**

The manufacturer shall establish the technical documentation in accordance with Article 17 of this Regulation.
3. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured product with the technical documentation referred to in point 2 of this Appendix and with the requirements set out in the relevant Appendices 1 to 6.
4. **CE marking and EU declaration of conformity**
  - 4.1. The manufacturer shall affix the CE marking and, when applicable, the UA class identification label in accordance with Articles 16 and 17 of this Regulation to each product that satisfies the applicable requirements set out in Appendices 1 to 6.
  - 4.2. The manufacturer shall draw up a written EU declaration of conformity for each product and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market. The EU declaration of conformity shall identify the product for which it has been drawn up.

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

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

***Conformity assessment Modules B and C — EU-type examination and conformity to type based on internal production control as per Annex II to Decision No 768/2008/EC***

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

**Module B**

**EU-type examination**

1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of the product and verifies and attests that the technical design of the product meets the applicable requirements set out in Appendices 1 to 6.
2. EU-type examination shall be carried out by an assessment of the adequacy of the technical design of the product through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the product (combination of production type and design type).
3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- (b) a written declaration that the same application has not been lodged with any other notified body;
- (c) the technical documentation. The technical documentation shall make it possible to assess the product's conformity with the applicable requirements of this Regulation and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall contain, wherever applicable, the elements set out in Article 18 of this Regulation;
- (d) the specimens representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme;
- (e) the supporting evidence for the adequacy of the technical design solution. That supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied or

have not been fully applied. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

4. The notified body shall:

For the product:

4.1 examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the product.

For the specimen(s):

4.2. verify that the specimen(s) has (have) been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards and/or technical specifications, as well as the elements which have been designed without applying the relevant provisions of those standards;

4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards and/or technical specifications, these have been applied correctly;

4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards and/or technical specifications have not been applied, the solutions adopted by the manufacturer meet the corresponding essential requirements of the legislative instrument;

4.5. agree with the manufacturer on a location where the examinations and tests will be carried out.

5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations as provided in point 8, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. Where the type meets the requirements of this Regulation, the notified body shall issue an EU-type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the aspects of the requirements covered by the examination, the conditions (if any) for its validity, and the necessary data for identification of the approved type. The EU-type examination certificate may have one or more annexes attached to it.

The EU-type examination certificate and its annexes shall contain all the relevant information to allow the conformity of the product 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 Regulation, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

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

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

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

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

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

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

## Module C

### Conformity to type based on internal production control

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

#### 2. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured product with the approved type described in the EU-type examination certificate and with the applicable requirements set out in Appendices 1 to 6.

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

3.1. The manufacturer shall affix the CE marking and, when relevant, the UA class identification label in accordance with Articles 16 and 17 of this Regulation to each product that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements set out in Appendices 1 to 6.

3.2. The manufacturer shall draw up a written EU declaration of conformity for each product type and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The EU declaration of conformity shall identify the product type for which it has been drawn up.

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

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

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



**Conformity assessment Module H — Conformity based on full quality assurance  
as per Annex II to Decision No 768/2008/EC**

1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the product concerned satisfies the applicable requirements set out in Appendices 1 to 6.

2. **Manufacturing**

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

3. **Quality system**

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

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- (b) the technical documentation for each type of product intended to be manufactured. The technical documentation shall contain, wherever applicable, the elements set out in Appendix 10;
- (c) the documentation concerning the quality system; and
- (d) a written declaration that the same application has not been lodged with any other notified body.

- 3.2. The quality system shall ensure compliance of the product with the requirements of this Regulation.

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

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

- (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;
- (b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards will not be applied in full, the means that will be used to ensure that the requirements of this Regulation will be met;

- (c) the design control and design verification techniques, processes and systematic actions that will be used when designing a product pertaining to the product type covered;
- (d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- (e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
- (f) the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel, etc.;
- (g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

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

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

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

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

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

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

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

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

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

- 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- 4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:
  - (a) the quality system documentation;
  - (b) the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.;
  - (c) the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel, etc.
- 4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.
- 4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may, if necessary, carry out UA or UAS tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

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

- 5.1. The manufacturer shall affix the CE marking and, when relevant, the UAS class identification label in accordance with Articles 16 and 17 of this Regulation and, under the responsibility of the notified body referred to in point 3.1 of this Appendix, the latter's identification number to each product that satisfies the applicable requirements of this Regulation.
- 5.2. The manufacturer shall draw up a written EU declaration of conformity for each product type and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The EU declaration of conformity shall identify the product type for which it has been drawn up.

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

6. The manufacturer shall, for a period ending 10 years after the product has been placed on the market, keep at the disposal of the national authorities:
  - (a) the technical documentation referred to in point 3.1;
  - (b) the documentation concerning the quality system referred to in point 3.1;
  - (c) the change referred to in point 3.5, as approved;

(d) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authority of the quality system approvals it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of the quality system approvals it has refused, suspended or otherwise restricted.

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

8. **Authorised representative**

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

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***Contents of technical documentation***

The technical documentation shall, wherever applicable, contain at least the following elements:

1. a complete description of the product including:
  - (a) photographs or illustrations showing its external features, markings and internal layout;
  - (b) the versions of any software or firmware involved in compliance with the essential requirements;
  - (c) user's manual and installation instructions;
2. conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits and other relevant similar elements;
3. descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product;
4. a list of the harmonised standards applied in full or in part, the references of which have been published in the *Official Journal of the European Union*, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements set out in Article 3, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
5. copy of the EU declaration of conformity;
6. where the conformity assessment module in Annex III has been applied, copy of the EU-type examination certificate and its annexes as delivered by the notified body involved;
7. results of design calculations made, examinations carried out, and other relevant similar elements;
8. test reports;
9. the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards and/or technical specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

**EU declaration of conformity**

1. The product (type, batch or serial number).
2. Name and address of the manufacturer or his authorised representative.
3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
4. Object of the declaration [*identification of the product allowing traceability; it may include a colour image of sufficient resolution where necessary for the identification of the products*].
5. The object of the declaration described above is of class ... [*include the class number of the UAS as defined by Appendices 1 to 5 to this Regulation*].
6. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation Regulation:
  - [*include the reference to this Regulation and the Annex relevant to the class of the product*];
  - or other Union harmonisation legislation where applicable.
7. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared. References must be listed with their identification number and version and, where applicable, date of issue.
8. Where applicable, the notified body ... [*name, number*] ... performed ... [*description of intervention*] ... and issued the EU-type examination certificate.
9. Where applicable, a description of accessories and components, including software, which allow the unmanned aircraft or unmanned aircraft system to operate as intended and covered by the EU declaration of conformity.
10. Additional information:

Signed for and on behalf of: ...

[*place and date of issue*]:

[*name, function*] [*signature*]:

***Simplified EU declaration of conformity***

The simplified EU declaration of conformity referred to in Article 12(9) shall be provided as follows:

[*Name of manufacturer*] hereby declares that the UA [*system*] type [*designation of type of UA or UA system*] is:

- of class ... .. [*include the class number of the product as defined in Appendices 1 to 5 of this Regulation*];
- and in compliance with Regulations ... [*list all the Regulations that the product complies with*].

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