

# 'Prototype' Commission Regulation on Unmanned Aircraft Operations

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22 AUGUST 2016

**Legal notice:** This document presents a 'prototype' regulation for to the operation of unmanned aircraft in the 'open' and 'specific' categories. Its sole purpose is to inform and consult stakeholders in view of the ongoing negotiations with the Parliament and the Council on the review of Regulation (EC) No 216/2008 and in view of giving indications on the possible direction that EASA will take on its implementation, after appropriate consultation, in a notice of proposed amendment (NPA) planned for the end of 2016. It represents the current views of EASA; however, it does not constitute any formal commitment on behalf of EASA nor of the European Commission.

PROTOTYPE



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**DRAFT COMMISSION REGULATION (EU) .../...**  
**of [...]**  
**laying down rules as regards unmanned aircraft operations**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to Regulation (EU) .../... of the European Parliament and of the Council of ... 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 and 51 thereof,

Having regard to 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 <sup>(2)</sup>,

Whereas:

- (1) Pursuant to Regulation (EU) .../... (hereinafter referred to as the 'Basic Regulation'), the Commission, assisted by the European Aviation Safety Agency (EASA), is empowered to adopt the necessary Commission acts for the design, production, maintenance and operation of unmanned aircraft systems (UASs) and their engines, propellers, parts, non-installed equipment and equipment to control them remotely.
- (2) Measures taken in the framework of this Regulation should be proportionate to the nature and risk of the type of unmanned aircraft operation and should in particular take due account of the following: type of operation and whether the operation is open to members of the public; the extent to which other air traffic or persons and property on the ground could be endangered by the operation; the type of airspace used and territory overflowed; the complexity and performance of the aircraft involved; the type, scale, and complexity of the operation or activity, including, where relevant, the size and type of the traffic handled by the responsible organisation or person.
- (3) The risk of operating an unmanned aircraft varies as a function of the characteristics of the unmanned aircraft and the type of operation. Therefore, different rules should apply to different categories taking into account the principles of proportionality and progressivity, and that rules should be based on risk assessment and be performance-based.
- (4) The higher risk operations of unmanned aircraft should be regulated by similar rules as for manned aircraft, which include the certification of the aircraft. The introduction of the regulatory framework to accommodate such 'certified' operations should therefore be the subject of a dedicated rulemaking process amending the existing regulations applicable to manned aircraft.
- (5) The lower risk operations, subject to the present Regulation, shall be regulated by less-stringent requirements based on an operation-centric concept. For these operations, which are subdivided

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<sup>(1)</sup> OJ L ...

<sup>(2)</sup> OJ L 122, 24.4.2014, p. 18.

into two categories (the 'open' and the 'specific' category), proportionate requirements should be applicable and adapted to the level of risks inherent to the category of operation. In order to reduce the administrative burden for operators and competent authorities, risk assessments should be conducted. The associated mitigating action should be identified in the form of 'standard scenarios' covering the types of operations carried out.

- (6) Regulation (EC) No 765/2008 <sup>(3)</sup> provides a framework for the market surveillance of products to ensure that those products fulfil requirements providing a high level of protection of public interests, such as health and safety in general, health and safety in the workplace, the protection of consumers, protection of the environment, and security. This Regulation also provides a framework for controls on products from third countries and lays down the general principles of the CE marking.
- (7) Decision No 768/2008/EC<sup>4</sup> provides, in the form of reference provisions, definitions and general obligations for economic operators and a range of conformity assessment procedures from which the legislator can select as appropriate. It also lays down rules for CE marking. Furthermore, reference provisions are provided as regards the requirements for conformity assessment bodies to be notified to the Commission as competent to carry out the relevant conformity assessment procedures and as regards the notification procedures. In addition, this Decision includes reference provisions concerning procedures for dealing with products presenting a risk in order to ensure the safety of the market place.
- (8) In order to ensure a smooth transition and to avoid disruptions, appropriate transitional measures should be provided.
- (9) The measures provided for in this Regulation take account of Opinion No .../... issued by EASA in accordance with Article ... of the Basic Regulation,

HAS ADOPTED THIS REGULATION:

### *Article 1*

#### **Subject matter and scope**

1. This Regulation lays down:
  - (a) rules for regulating an operation-centric concept for the operation of unmanned aircraft (UA), and more specifically in the 'open' and 'specific' categories, within the single European sky airspace.
  - (b) technical requirements and administrative procedures for the design, production and maintenance of UASs in the 'open' and 'specific' categories within the European Union, as applicable;
  - (c) technical requirements and administrative procedures for the implementation of the concepts of registration, electronic identification, and geofencing;

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<sup>(3)</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>(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).

- (d) requirements for subcategories in the 'open' category;
  - (e) conditions to issue a declaration or to obtain an authorisation, as appropriate, in the 'specific' category;
  - (f) requirements for the introduction of a concept of standard scenarios in the 'specific' category;
  - (g) conditions to obtain an optional light UA operator certificate (LUC), with associated privileges; and
  - (h) conditions for the making available on the market of UASs intended to be used for operations in the 'open' category, as well as requirements for market surveillance relating to the marketing of those UASs in the Union. Those conditions shall constitute Community harmonisation legislation within the meaning of Regulation (EC) No 765/2008 and of Decision No 768/2008/EC.
2. Operations in the 'certified' category are not subject to this Regulation.

## *Article 2*

### **Definitions**

1. For the purposes of this Regulation, the definitions of Article 3 of the Basic Regulation, of Article 2 of Regulation (EC) No 765/2008, and of Article R1 of Annex I to Decision No 768/2008/EC shall apply.
2. For the purposes of this Regulation, the following definitions shall also apply:
  - (a) 'acceptable means of compliance' (AMC) means non-binding standards adopted by EASA which may be used by persons and organisations to demonstrate compliance with the Basic Regulation and its Commission acts;
  - (b) 'AIS' means 'Abbreviated Injury Scale' and it is an anatomically based coding system created by the Association for the Advancement of Automotive Medicine to classify and describe the severity of injuries;
  - (c) 'automatic flight' means a flight following preprogrammed instructions, loaded in the unmanned aircraft (UA) flight control system, that the UA executes;
  - (d) 'certification specifications' (CSs) means non-binding technical standards adopted by EASA which indicate the means to demonstrate compliance with the Basic Regulation and its Commission acts, and which can be used by organisations for the purpose of certification;
  - (e) 'competent authority' means the authority responsible for the certification, authorisation and oversight of UAS air operations in the Member State where the UAS operator has its principal place of business or place of residence;
  - (f) 'electronic identification' means the capability to identify a UA in flight without direct physical access to that aircraft;
  - (g) 'first-person-view mode' means a mode of operation of a UA where the remote pilot monitors the UA position through a camera installed on the aircraft;
  - (h) 'follow-me mode' means an automatic mode of operation of a UAS where the UA constantly follows a device;

- (i) 'geographical limitation' means a restricted airspace volume defined through electronic map data;
- (j) 'geofencing' means an automatic function to limit the access of the UA to airspace areas or volumes provided as geographical limitations based on the UA position and navigation data;
- (k) 'guidance material (GM)' means non-binding material developed by EASA that helps to illustrate the meaning of a requirement or specification and is used to support the interpretation of the Basic Regulation, its Commission acts, certification specifications and acceptable means of compliance;
- (l) 'hazard' means a condition or an object with the potential to cause injuries, damage, loss of material or a reduction of the ability to perform a prescribed function;
- (m) 'operator of a UA' means any natural or legal person who operates or intends to operate a UA;
- (n) 'Part-UAS' means the rules applicable to the operation of a UA falling into the 'open' or 'specific' category, as laid down in Annex I to this Regulation;
- (o) 'placing on the market' shall mean the first time a product is made available on the EU market;
- (p) 'remote pilot' is a natural person who manipulates the flight controls of a UA, as appropriate, during a flight and is responsible for safely conducting the flight;
- (q) 'remote pilot competency' means a combination of skills, knowledge and attitudes required to perform a task to the prescribed standard;
- (r) 'remote pilot station' (RPS) means a component of the UAS containing the equipment used to control the UA;
- (s) 'standard scenario' means a description of a type of operation included in a certification specification issued by EASA, for which a specific operations risk assessment (SORA) has been conducted;
- (t) 'UA' (unmanned aircraft) means any aircraft operated or designed to be operated without a pilot on board;
- (u) 'UA observer' means a natural person who, by visual observation of the UA, assists the remote pilot in safely conducting the flight;
- (v) 'UA system' (UAS) means the UA and any equipment, apparatus, appurtenance, software or accessory that is necessary for the safe operation of the UA;
- (w) 'visual line of sight' (VLOS) means a type of operation in which the remote pilot maintains continuous unobstructed and unaided visual contact with the UA, allowing the remote pilot to monitor the flight path of the UA in relation to other aircraft, persons, and obstacles, for the purpose of maintaining separation from them and avoiding collisions.

3. The definitions relative to product legislation are listed in Annex II.

### *Article 3*

#### **Categories of UA operations**

UA operations shall fall into one of the following three risk-based categories:

1. 'open' is a category of UA operation that, considering the risks involved, does not require a prior authorisation by the competent authority before the operation takes place;
2. 'specific' is a category of UA operation that, considering the risks involved, requires an authorisation by the competent authority before the operation takes place and takes into account the mitigation measures identified in an operational risk assessment, except for certain standard scenarios where a declaration by the operator is sufficient;
3. 'certified' is a category of UA operation that, considering the risks involved, requires the certification of the UA, a licensed remote pilot and an operator approved by the competent authority, in order to ensure an appropriate level of safety.

### *Article 4*

#### **Principles for UA operations**

1. The operator of a UA shall be responsible for its safe operation. The operator shall comply with the requirements laid down in this Regulation and other applicable regulations, in particular those related to security, privacy, data protection, liability, insurance and environmental protection.
2. The operator of a UA shall register with the competent authority and display registration marks on all the UA it operates in order for them to be easily identifiable, when required by UAS.OPEN.30 and UAS.SPEC.40.
3. The operator shall ensure that UA are equipped with an electronic identification means, when required by UAS.OPEN.70 and UAS.OPEN.80.
4. The operator shall ensure that UA are equipped with a geofencing function, when required by UAS.OPEN.70 and UAS.OPEN.80.
5. The competent authorities may designate zones or airspace areas where UA operations are prohibited or restricted, in accordance with Article 12.

### *Article 5*

#### **'Open' category operations**

1. For operations in the 'open' category, risks shall be mitigated through a combination of safety measures, including:
  - (a) requirements and limitations on the operation, the UAS, and the personnel and organisations involved as detailed in Annex I to this Regulation; and
  - (b) limitations to be defined by the competent authority for geofencing purposes or for particular airspace areas.



2. Considering the different levels of risk within an 'open' category operation, this category is further divided into subcategories of operations. Each subcategory of operation is characterised by:
  - (a) the use of a specific class of UAS defined by the technical requirements provided in the related appendix;
  - (b) operational limitations; and
  - (c) requirements for the remote pilot and operator, as appropriate.
3. Except for privately built UASs in subcategory A0, the requirements defining the different classes of UASs operated or intended to be operated in the 'open' category shall constitute Community harmonisation legislation within the meaning of Regulation (EC) No 765/2008 and of Decision No 768/2008/EC. The placing on the market of UASs of those classes shall comply with the conditions and rules set out in Annex II to this Regulation.
4. An operation of a UA conducted in the 'open' category within the single European sky airspace shall comply with the requirements of Subpart A of Annex I to this Regulation.

#### *Article 6*

#### **'Specific' category operations**

1. For operations in the 'specific' category, risks shall be mitigated through safety measures identified in an operational risk assessment or contained in a standard scenario published by EASA.
2. In order to be able to operate in the 'specific' category, the operator shall comply with the conditions specified in:
  - (a) the standard scenario, where a declaration is considered sufficient;
  - (b) an operational authorisation issued by the competent authority; or
  - (c) an operational authorisation issued by the holder of a light UA operator certificate (LUC) with privileges to authorise its operations.
3. An operation of a UA conducted in the 'specific' category within the single European sky airspace shall comply with the requirements of Subpart B of Annex I to this Regulation.

#### *Article 7*

#### **Safety-critical services**

1. The provider of any safety-critical services is responsible for the accuracy and integrity of the provided information and data, and for the quality of the services.
2. The provider shall have a suitable organisational structure, appropriate documented procedures, and adequate resources and personnel.
3. Services may include but are not limited to:
  - (a) providing geographical data and limitations;
  - (b) collecting and forwarding occurrence data;
  - (c) the training of pilots.

## Article 8

### **Designation of the competent authority**

1. As laid down in the Basic Regulation, a Member State shall designate one or more competent authorities, with allocated responsibilities for the authorisation and oversight of UA operations.
2. If a Member State designates more than one entity as a competent authority:
  - (a) the areas of competence of each entity shall be clearly defined; and
  - (b) coordination shall be established between those entities to ensure effective implementation of this Regulation.
3. The Member State shall designate competent authorities that:
  - (a) have a suitable organisational structure, appropriate documented procedures, and adequate resources;
  - (b) have personnel with sufficient knowledge, experience and training to perform their allocated tasks.
4. Member States shall ensure that the competent authority personnel do not perform activities related to this Regulation when there is evidence that this could result, directly or indirectly, in a conflict of interest, in particular when related to family or financial interest.
5. Member States shall ensure that the competent authority safeguards the objectivity and impartiality of its activities.

## Article 9

### **Responsibilities of the competent authority**

1. The competent authority shall:
  - (a) examine documents, records and reports relevant to UA operations, remote pilots or operators;
  - (b) develop an oversight programme on an annual basis, including audits and inspections, as appropriate and proportionate to the identified risks;
  - (c) take into account the results of past oversight activities and the safety priorities when defining the scope of the oversight programme;
  - (d) inspect as required UASs, remote pilots and operators to determine their compliance with this Regulation;
  - (e) issue, suspend, revoke or amend certificates and authorisations to carry out the types of operations referred to in this Regulation;
  - (f) establish and maintain a register of UA operators, and a register(s) of declarations, authorisations and certificates;
  - (g) have a system to detect and analyse non-compliances by declared organisations, or by organisations it has authorised or certified, and shall limit, suspend or revoke an authorisation or certificate or impose other measures or sanctions as applicable;



- (h) approve, restrict or prohibit airspace areas or define special zones, and make this information available;
  - (i) establish enforcement measures and sanctions;
2. The responsibilities and tasks of the competent authority shall be carried out in accordance with the legal provisions of the relevant Member State.

*Article 10*

**Exchange of safety information**

Competent authorities designated under Article 8 and the notifying authorities defined in Annex II Article II.18 shall set up a network to organise and implement cooperation on safety matters, including the establishment of a system to exchange safety information and to ensure the interoperability of the registers referred to in Article 9(1)(f) through a standardised interface(s).

*Article 11*

**Means of compliance**

1. EASA shall develop acceptable means of compliance (AMC) and certification specifications (CSs) that may be used to establish compliance with the Basic Regulation and its Commission acts. When AMC are complied with, the related requirements of the Commission acts are met.
2. Alternative means of compliance may be used to establish compliance with the Basic Regulation and its Commission acts.
3. The competent authority shall establish a system to consistently evaluate that all alternative means of compliance used by itself or by organisations and persons under its oversight allow the establishment of compliance with the Basic Regulation and its Commission acts.
4. The competent authority shall evaluate all alternative means of compliance proposed by an organisation by analysing the documentation provided and, if considered necessary, conducting an inspection of the organisation.

When the competent authority finds that the alternative means of compliance are in accordance with the Basic Regulation and its Commission acts, it shall, without undue delay:

- (a) notify the applicant that the alternative means of compliance may be implemented and, if applicable, amend the operational authorisation or certificate of the applicant accordingly;
  - (b) notify EASA of their content, including copies of all relevant documentation;
  - (c) inform other Member States about alternative means of compliance that were accepted.
5. When the competent authority itself uses alternative means of compliance to achieve compliance with the Basic Regulation and its Commission acts, it shall:
- (a) make them available to all organisations and persons under its oversight; and
  - (b) without undue delay, notify EASA.
6. The competent authority shall provide EASA with a full description of the alternative means of compliance, including any revisions to procedures that may be relevant, as well as an assessment demonstrating that the Commission acts are met.

*Article 12*

**Airspace areas or special zones for UA operations**

1. Based on the categories of operation and required mitigation measures, the competent authorities shall define airspace areas or special zones:
  - (a) where UA operations are not permitted without prior authorisation or are not permitted at all;
  - (b) where UA shall comply with defined technical or performance specifications, including mandatory equipment or functions that enable easy identification or automatically limit the airspace they can enter (geofencing);
  - (c) where UA operations shall comply with specified environmental standards.
2. The information on prohibited, restricted and special zones for UA operations, as well as on required authorisations, shall be made available in a manner and format acceptable to EASA.

*Article 13*

**Immediate reaction to a safety problem**

1. EASA and the competent authorities shall collect, analyse and disseminate safety information concerning UA operations in their territory in accordance with the Basic Regulation and its Commission acts.
2. Upon receiving the information referred to in 1. above, EASA or the competent authority shall take adequate measures to address safety problems.
3. Measures taken under 2. above shall immediately be notified to all persons or organisations which need to comply with such measures under the Basic Regulation and its Commission acts. Competent authorities shall also notify those measures to EASA, if it has not been addressed, and, when combined action is required, to the other Member States concerned.

*Article 14*

**Applicability**

1. As from [2 years after entry into force of this Regulation — estimate 2019], economic operators and UASs placed on the market shall comply with this Regulation.
2. UASs placed on the market before [2 years after entry into force of this Regulation — 2019] and having a mass of 250 g or less, including payload, are deemed to be classified as class 0 as defined in Appendix I.2 and can continue to be operated according to operational subcategory A0 defined in UAS.OPEN.60.
3. As from [3 years after entry into force of this Regulation — estimate 2020], all UA shall be operated in accordance with this Regulation.
4. By [3 years after entry into force of this Regulation — estimate 2020], all operators shall convert their existing authorisations into authorisations or declarations as required by this Regulation.

*Article 15*

**Transitional provisions**

For recreational operations of UA, such as leisure flights, air displays, sport or competition activities, conducted in the frame of associations or clubs with proven satisfactory safety records and performed under national systems before this Regulation enters into force, the following transitional provisions shall apply:

1. By [3 years after entry into force of this Regulation — estimate 2020], the competent authority shall issue operational authorisations to associations or clubs for the operations which would otherwise require an authorisation according to Subpart B of Annex I to this Regulation.
2. An operational authorisation can be issued without the need to conduct the operational risk assessment referred to in UAS.SPEC.60.
3. Operational authorisations issued under this Article shall define the conditions, limitations and deviations from the requirements of Subpart B of Annex I to this Regulation.

*Article 16*

**Entry into force and application**

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

It shall apply from [...].

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

## **ANNEX I**

### **Operation of UA in the 'open' and 'specific' categories**

#### **[PART-UAS]**

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## SUBPART A

### ***OPEN CATEGORY***

#### **UAS.OPEN.10 Subcategories of operations**

Operation of UA in the 'open' category shall fall into one of the following subcategories:

- (a) subcategory A0: operation of UA posing a negligible risk of severe injury to people on the ground or damage to manned aircraft, and requiring neither specific remote pilot competence nor age limitations;
- (b) subcategory A1: operation of UA complying with requirements ensuring that they pose a negligible risk of severe injury to people on the ground or damage to manned aircraft, and requiring neither specific remote pilot competence nor strict operational limitations;
- (c) subcategory A2: operation of UA complying with requirements ensuring that they pose a limited risk of severe injury to people on the ground or damage to manned aircraft, operated by registered operators, and equipped with geofencing and electronic identification;
- (d) subcategory A3: operation of UA complying with requirements imposing technical mitigations like geofencing and electronic identification, posing a higher risk of severe injuries to people on the ground or damage to manned aircraft and operated by registered operators with higher competence.

#### **UAS.OPEN.20 Responsibilities of the operator**

- (a) The operator of a UA shall have the ultimate responsibility for the operation of that UA.
- (b) When applicable, the operator of a UA shall designate a remote pilot for each operation.
- (c) The operator shall:
  - (1) comply with the regulations applicable in all Member States affected by the operation, in particular those related to safety, privacy, data protection, liability, insurance, security and environmental protection;
  - (2) ensure that prior to conducting operations, remote pilots and all other personnel are competent for the performance of their tasks and are familiar with the operator's policy and procedures; and
  - (3) prepare and maintain a list of personnel with assigned duties, if applicable.

#### **UAS.OPEN.30 Registration of UA operators**

Except when operating in subcategory A0 or when already registered in the 'specific' category, the operator of a UA shall:

- (a) register in the Member State where they have their permanent residence, or a principal place of business, using the form in Appendix I.1;
- (b) in the case of a legal person, include in the registration form in Appendix I.1 a description of the structure of the organisation, including a statement that the UA will be operated only by remote pilots with a level of competency appropriate for conducting operations with a UA and appropriate to the category of the UAS; and
- (c) display the registration number on the UA.

#### **UAS.OPEN.40 Requirements applicable to all UA operations in the 'open' category**

- (a) The remote pilot shall:
- (1) be in a physical and mental condition that would not put at risk the safe operation of the UA, other aircraft, people, or property and shall not operate when adversely affected by drugs or alcohol; and
  - (2) where the remote pilot is also the operator, comply with UAS.OPEN.20 and UAS.OPEN.30.
- (b) Before the initiation of any UA operation, the remote pilot shall:
- (1) obtain updated information about any flight restrictions or conditions published by the competent authority that may be relevant to the intended operation;
  - (2) familiarise themselves with the operating environment, including the locations of people, properties and any other hazards; and
  - (3) check that:
    - (i) the UAS is in a safe condition to accomplish the intended flight, and where applicable, has been updated with geofencing data and recovery procedures; and
    - (ii) the UAS complies with the user manual (or equivalent) provided by the manufacturer.
- (c) During flight, the remote pilot shall:
- (1) comply with the requirements applicable to the UA operational subcategory;
  - (2) avoid reckless manoeuvres with the UA;
  - (3) comply with the limitations defined by the competent authority for the area, zone or airspace;
  - (4) ensure the safe operation of the UA, including a safe separation of the UA from people, property, ground vehicles, public roads and from other airspace users;
  - (5) discontinue a flight when continuing the flight would pose a hazard to other aircraft, people, or properties;
  - (6) operate the UA within the performance limitations defined in the user manual (or equivalent) provided by the manufacturer;
  - (7) not use the UA to transport dangerous goods or passengers;
  - (8) not fly close to areas where an emergency response effort is ongoing; and
  - (9) respect other people's fundamental rights and operate the UA in a considerate way to minimise nuisance to other people from noise emissions.

#### **UAS.OPEN.50 Requirements applicable to UA operations in subcategory A0**

UA operations in subcategory A0 shall:

- (a) be performed:
- (1) either with a class 0 UAS placed on the market:



- (i) complying with Directive 2009/48/EC <sup>(5)</sup> on the safety of toys and the product's requirements defined in Appendix I.2;
  - (ii) displaying the CE (Conformité Européene) marking and the class 0 identification label on the UA in a visible and practical manner; and
  - (iii) not be modified in a way that breaches compliance with the requirements in Appendix I.2; or
- (2) with a privately built UAS complying with the following:
- (i) the UA has a maximum take-off mass, including payload, of less than 250 g and its maximum ground speed is less than 15 m/s; or
  - (ii) in the case of a tethered aircraft, the maximum length of the tether is 50 m, it has no propulsion system, and:
    - a. its maximum take-off mass, including payload, is less than 25 kg; or
    - b. in the case of lighter-than-air aircraft, the volume is less than 40 m<sup>3</sup>;
- (b) be conducted:
- (1) up to a height of 50 m (150 ft) above ground level;
  - (2) within a range such that the remote pilot maintains visual line of sight (VLOS) and the UA does not exceed a horizontal distance of 100 m from the remote pilot; or
  - (3) in first-person-view mode or follow-me mode, only if the remote pilot maintains a safe separation of the UA from people, property, ground vehicles, public roads and from other airspace users.

#### **UAS.OPEN.60 Requirements applicable to UA operations in subcategory A1**

UA operations in subcategory A1 shall:

- (a) be performed with a class 1 UAS placed on the market:
  - (1) complying with the product requirements defined in Appendix I.3;
  - (2) displaying the CE marking and the class 1 identification label on the UA in a visible and practical manner;
  - (3) displaying the registration number of the operator in a visible and practical manner; and
  - (4) that has not been modified in a way that breaches compliance with the product requirements in Appendix I.3;
- (b) be conducted:
  - (1) up to a height of 50 m (150 ft) above ground level unless otherwise limited by the competent authority for the operation area; and
  - (2) within a range such that the remote pilot maintains VLOS; or
  - (3) in first-person-view mode or follow-me mode, only if the remote pilot maintains a safe separation of the UA from people, property, ground vehicles, public roads and from other airspace users;

<sup>(5)</sup> OJ L 170, 30.6.2009, p. 1.

- (c) be carried out by a remote pilot being at least 14 years old.

**UAS.OPEN.70 Requirements applicable to UA operations in subcategory A2**

UA operations in subcategory A2 shall:

- (a) be performed with a class 2 UAS placed on the market:
- (1) complying with the product requirements defined in Appendix I.4;
  - (2) displaying the CE marking and the class 2 identification label on the UA in a visible and practical manner;
  - (3) displaying the registration mark of the operator in a visible and practical manner; and
  - (4) that has not been modified in a way that breaches compliance with the requirements in Appendix I.4;
- (b) be conducted:
- (1) up to a height of 50 m (150 ft) above ground level;
  - (2) within a range such that the remote pilot maintains VLOS;
  - (3) with a minimum horizontal distance of 50 m from uninvolved persons; and
  - (4) with active and up-to-date geofencing and electronic identification systems;
- (c) be carried out by a remote pilot:
- (1) being at least 14 years old; and
  - (2) having the appropriate familiarisation according to the user manual.

**UAS.OPEN.80 Requirements applicable to UA operations in subcategory A3**

UA operations in subcategory A3 shall:

- (a) be performed with a class 3 UAS placed on the market:
- (1) complying with the product requirements defined in Appendix I.5;
  - (2) displaying the CE marking and the class 3 identification label on the UA in a visible and practical manner; and
  - (3) that has not been modified in a way that breaches compliance with the requirements in Appendix I.5;
- (b) be conducted:
- (1) up to a height of 150 m (500 ft) above ground level, unless otherwise determined by the competent authority for the operational area based on airspace considerations;
  - (2) within a range such that the remote pilot, or a UA observer who is situated within the VLOS of the remote pilot, maintains VLOS; clear and effective communication shall be established between the remote pilot and the UA observer;
  - (3) with a minimum horizontal distance of 20 m from uninvolved persons if flying a rotorcraft, or 50 m otherwise; and
  - (4) with active and up-to-date geofencing and electronic identification systems;
- (c) and be carried out by a remote pilot:

- (1) being at least 14 years old;
- (2) carrying evidence of the competence achieved after having received training provided by training service providers in general knowledge of aviation and airspace, principles of operation of UA, risk management, ethical airmanship, data protection, privacy protection and environmental protection according to standards or alternative qualifications accepted by EASA;
- (3) having the appropriate familiarisation or practical training to minimise the risk to third parties in the specific conditions and operational environment, following best practices.

#### **UAS.OPEN.90 Occurrence reporting**

In the event of a fatal or serious injury to a person or when an aircraft other than a UA is involved, the operator shall report the occurrence and other safety-related information regarding the UAS, in compliance with Regulation (EU) No 376/2014.

PROTOTYPE

SUBPART B  
***SPECIFIC CATEGORY***

**UAS.SPEC.10 Responsibilities of the operator**

- (a) The operator of UA shall have the ultimate responsibility for their operation.
- (b) When applicable, the operator of UA shall designate a remote pilot for each operation.
- (c) The operator shall:
  - (1) comply with the regulations applicable in all Member States affected by the operation, in particular those related to safety, privacy, data protection, liability, insurance, security and environmental protection;
  - (2) ensure that prior to conducting operations, remote pilots and all other personnel are competent for the performance of their task and are familiar with the operator's policies and procedures;
  - (3) comply with the 'standard scenario' requirements when applicable;
  - (4) unless the local conditions of the place where the operation takes place impose additional limitations, carry out an operation within the limitations and conditions specified in the operational authorisation or operational declaration, as applicable; and
  - (5) prepare and maintain a list of personnel with assigned duties if applicable.

**UAS.SPEC.20 Registration of UA operators**

Except when already registered in the 'open' category, the operator of a UA shall:

- (a) register in the Member State where the operator has its permanent residence, or a principal place of business, using the form in Appendix I.1;
- (b) in the case of a legal person, include in the registration form in Appendix I.1 a description of the structure of the organisation, including a statement that the UA will be operated only by remote pilots with a level of competency appropriate for conducting operations with that UA and appropriate to the category of UA operation; and
- (c) display the registration identification on the UA.

**UAS.SPEC.30 Requirements applicable to all UA operations in the 'specific' category**

The remote pilot shall:

- (a) be in a physical and mental condition that would not put at risk the safe operation of the UA, other aircraft, people, or property and not operate when adversely affected by drugs or alcohol; and
- (b) where the remote pilot is also the operator, comply with UAS.SPEC.10 and UAS.SPEC.20.

Before the initiation of a UA operation, the remote pilot shall:

- (a) obtain updated information about any flight restrictions or conditions published by the competent authority that may be relevant to the intended operation;
- (b) familiarise themselves with the operating environment, including the locations of people, properties and any other hazards;

- (c) check that the UAS is in a safe condition to accomplish the intended flight, and where applicable, has been updated with geofencing data and recovery procedures;
- (d) be familiar with the operations manual for the specific type of the operation; and
- (e) ensure that the operating conditions, including environmental conditions, are compatible with the authorised conditions and limitations.

During flight, the remote pilot shall:

- (a) avoid reckless manoeuvres with the UA;
- (b) comply with the limitations defined by the competent authority for the area or airspace;
- (c) ensure the safe operation of the UA, including a safe separation of the UA from people, property, ground vehicles, public roads and from other airspace users;
- (d) discontinue a flight when continuing the flight would pose a hazard to other aircraft, people or properties;
- (e) operate the UA within the performance limitations defined in the user manual (or equivalent) provided by the manufacturer;
- (f) respect the limitations defined by the competent authority for the restricted or prohibited areas or airspace, where the operation takes place;
- (g) not use the UA to transport passengers;
- (h) not fly close to areas where an emergency response effort is ongoing; and
- (i) respect other people's fundamental rights and operate the UA in a considerate way to minimise nuisance to other people from noise emissions.

#### **UAS.SPEC.40 Operational declaration**

- (a) Except when holding an LUC per Subpart C of this Annex, with the appropriate privileges, and where the relevant 'standard scenario' published by EASA so requires, the operator shall submit an operational declaration to the competent authority in accordance with the form in Appendix I.7.
- (b) The operational declaration shall include all information relevant for the intended operations, a statement of compliance with the limitations and conditions applicable to the relevant 'standard scenario', and a signed acknowledgement of responsibility under this Regulation.
- (c) Upon receipt of the declaration submitted by a UA operator, the competent authority shall verify that the declaration contains all the information and documents referred to in (b).
- (d) Upon submission of the operational declaration, the operator shall be entitled to start the operation as long as it corresponds to a 'standard scenario' published by EASA.
- (e) The operator shall notify the competent authority, without delay, of any changes to the statements and information submitted in the operational declaration.

#### **UAS.SPEC.50 Application for an operational authorisation**

- (a) Except when holding an LUC per Subpart C of this Annex, with the appropriate privileges, the operator shall submit an application for operational authorisation to the competent authority in accordance with the form in Appendix I.9 prior to starting an operation that:

- (1) corresponds to a 'standard scenario' published by EASA and requesting an operational authorisation; or
  - (2) does not correspond to a 'standard scenario'.
- (b) The application shall include all the information relevant to the operation and a statement of compliance with the limitations and conditions applicable to the relevant 'standard scenario', if applicable, and a signed acknowledgement of responsibility under this Regulation.
  - (c) The operator shall only start the proposed operation after having received the operational authorisation issued by the competent authority in accordance with the form in Appendix I.8.
  - (d) Any change to the operation not covered by the authorisation or by a 'standard scenario' published by EASA shall require the submission of a new application for an operational authorisation under this Regulation.

#### **UAS.SPEC.60 Operational risk assessment**

- (a) EASA shall approve and publish 'standard scenarios' and their associated ranges of mitigating measures for the types of operations for which a risk assessment has been conducted and for which mitigating measures have been identified.
- (b) If the operation does not correspond to any of the 'standard scenarios' published by EASA, the operator shall conduct a risk assessment of the proposed operation and identify mitigation measures to be put in place in order to limit the risk to an acceptable level. The operator shall consider the following key factors:
  - (1) the operational area and conditions;
  - (2) the category of airspace and the effects on other air traffic and air traffic management (ATM);
  - (3) the design features and performance of the UAS;
  - (4) the type of operation;
  - (5) the level of competence of the remote pilot;
  - (6) organisational factors; and
  - (7) effects on the environment.
- (c) Except when holding an LUC per Subpart C of this Annex, the operator shall provide the competent authority with the risk assessment.

#### **UAS.SPEC.70 Operations manual**

If the operation does not correspond to any of the 'standard scenarios' published by EASA or if required by the relevant 'standard scenario', the operator shall compile an operations manual adapted to the type of operation.

#### **UAS.SPEC.80 Issuing of an operational authorisation**

- (a) Upon receipt of an application for the issuing of an operational authorisation from a UA operator, the competent authority shall verify that the application contains all the information and documentation required.



- (b) The competent authority shall issue an authorisation using the form in Appendix I.8 to an operator to conduct an operation under a 'specific' category when:
  - (1) it concludes that the operation corresponds to a 'standard scenario' published by EASA for which an authorisation is required, and:
    - (i) it is satisfied that the means of mitigation required by the 'standard scenario' have been adequately put in place by the operator; and
    - (ii) it has found the operations manual referred to in UAS.SPEC.70 to be acceptable;
  - (2) the type of operation does not correspond to a 'standard scenario' and:
    - (i) it is satisfied with the risk assessment provided by the operator;
    - (ii) it is satisfied that the means of mitigation necessary to limit the risk to an acceptable level have been adequately established by the operator; and
    - (iii) it has found the operations manual required by UAS.SPEC.70 to be acceptable.
- (c) The authorisation may be issued for a limited or an unlimited duration. The conditions under which an operator is authorised to conduct the intended operation shall be specified in the authorisation.
- (d) If there are changes to the operational conditions for which an operator has received an operational authorisation, the competent authority may decide whether the authorisation shall be suspended, revoked or amended.

#### **UAS.SPEC.90 UAS logbook**

Where required in the operational authorisation, the operator shall ensure that, as a minimum, records of completion of preflight or postflight checks, time in service, and of defects and repairs with regard to the UAS are retained in the form of a logbook, or equivalent.

#### **UAS.SPEC.100 Use of certified equipment and certified UA**

- (a) If the operation relies on certified UA or certified equipment, the operator shall record the operation or service time according to the instructions and procedures applicable to the certified equipment or the organisational approval or authorisation.
- (b) The operator shall follow the instructions for continued airworthiness for the equipment or the UA and comply with mandatory directives published by EASA.

#### **UAS.SPEC.120 Occurrence reporting**

The operator shall report to the competent authority any operation of the UA that involves an injury to any person or damage to any property, vehicle, or another aircraft in accordance with Regulation (EU) No 376/2014.

## SUBPART C

### *LIGHT UA OPERATOR CERTIFICATE (LUC)*

#### **UAS.LUC.10 Application for a light UA operator certificate (LUC)**

- (a) The operator may apply for an LUC to the competent authority.
- (b) The operator shall submit an application using the form in Appendix I.10 including:
  - (1) the relevant information for the application;
  - (2) a description of their management system, including their organisational structure and safety management system;
  - (3) the name(s) of the responsible personnel, including the person responsible for authorising operations with UA; and
  - (4) a statement that all the documentation submitted to the competent authority has been verified by the applicant and found to comply with the applicable requirements.
- (c) The operator shall only start an operation after having received an LUC issued by the competent authority in accordance with this Regulation.

#### **UAS.LUC.20 Management system**

- (a) The LUC holder shall establish, implement and maintain a management system that includes:
  - (1) a safety policy and clearly defined lines of responsibility and accountability throughout the organisation, including the direct accountability for safety of the responsible personnel;
  - (2) the identification of the aviation safety hazards entailed by the activities of the operator, their evaluation and the management of the associated risks, including taking action to mitigate the risk and verify the effectiveness of the action;
  - (3) documentation of all management system key processes, including a process for making personnel aware of their responsibilities and the procedure for amending this documentation; and
  - (4) a function to monitor the compliance of the operator with the established mitigations and requirements.
- (b) The LUC holder shall appoint a safety manager.
- (c) For organisations having a workforce of more than 20 full-time equivalents (FTEs) involved in the UA operations and maintenance, a safety board shall be established.

#### **UAS.LUC.30 Record-keeping**

- (a) The operator shall establish a record-keeping system that allows adequate storage and reliable traceability of all activities developed, covering in particular all the elements indicated in UAS.LUC.20.
- (b) The format of the records shall be specified in the operator's procedures.

- (c) Records shall be stored in a manner that ensures protection from unauthorised access, damage, alteration and theft.

**UAS.LUC.40 Issuing a light UA operator certificate (LUC)**

- (a) The competent authority shall issue an LUC in accordance with the form in Appendix I.11 after it is satisfied that the operator complies with UAS.LUC.10, UAS.LUC.20 and UAS.LUC.30.
- (b) The LUC shall include the operator's privileges and operational limitations where applicable.
- (c) An operator holding an LUC shall have the privilege to authorise its own operations within its scope of approval.

PROTOTYPE

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*APPENDICES*

**Required forms for authorisations, certificates and products**

**EASA FORMS**

When the forms of this Annex are issued in a language other than English, an English translation shall be included.

The EASA ('European Aviation Safety Agency') forms referred to in the appendices to this Part shall have the following mandatory features. Member States shall ensure that the EASA forms they issue are recognisable and shall be responsible for having those forms printed.

PROTOTYPE

*Appendix I.1*

**UA operator registration form**

TBD

*[The form shall contain at least the following:*

- a) Name of the operator (or the business name, if a company), postal address, and mailing address;*
- b) If it is an organisation, it needs to state the following:*

*All UA operations shall comply with this Regulation, remote pilots shall be sufficiently trained and informed of the UAS limitations and permitted fly zones, areas or airspaces.]*

PROTOTYPE

*Appendix I.2*

**Product requirements for class 0 UASs**

This Appendix constitutes Community harmonisation legislation within the meaning of Regulation (EC) No 765/2008 and of Decision No 768/2008/EC for class 0 UASs, while the conformity assessment procedure is defined in Annex II Article II.12.

A class 0 UAS shall comply with Directive 2009/48/EC on the safety of toys and shall:

- (a) have a maximum take-off mass, including payload, of 250 g;
- (b) have performance limitations or an active system limiting the attainable height of the UA to a maximum of 50 m above the ground level, limiting the distance of the UA to 100 m from the remote pilot, and the maximum ground speed of the UA shall be less than 54 km/h (15 m/s);
- (c) be safely controllable without any training courses;
- (d) bear the following label on the UA in a visible manner:



- (e) be placed on the market with clear operational instructions and warnings highlighting the risks related to UAS operations, adapted to the age of the user;
- (f) include information required to use the UAS in accordance with the applicable regulations on aviation safety, security, privacy and data protection, liability and insurance and the awareness leaflet defined in Appendix I.12.



*Appendix I.3***Product requirements for class 1 UASs**

This Appendix constitutes Community harmonisation legislation within the meaning of Regulation (EC) No 765/2008 and of Decision No 768/2008/EC for class 1 UASs, while the conformity assessment procedure is defined in Annex II Article II.12.

A class 1 UAS shall:

- (a) be made of materials, and shall have performance and physical characteristics, such as to guarantee that, in the event of an impact with a human body, the severity of the injuries that can be inflicted by the UA does not exceed AIS level 2; in any case, the UAS must have a maximum take-off mass (MTOM), including payload, of less than 25 kg;
- (b) have performance limitations or an active system limiting the attainable height of the UA to a maximum of 50 m above the ground level;
- (c) be safely controllable without any training courses;
- (d) comply with the following requirements:

*I. Physical and mechanical properties*

1. The UAS must have the requisite mechanical strength and, where appropriate, stability, to withstand the stresses to which it is subjected during use without breakage or deformation interfering with its safe flight.

*II. Flammability*

- 1. The UAS must not constitute a dangerous flammable element in its normal operational environment.
- 2. The UAS must not be explosive or contain elements or substances likely to explode.

*III. Electrical properties*

1. The UAS shall not be powered by electricity of a nominal voltage exceeding 24 volts direct current (DC) or the equivalent alternating current (AC) voltage, and its accessible parts shall not exceed 24 volts DC or the equivalent AC voltage.

Internal voltages shall not exceed 24 volts 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 broken.

- 2. Parts of the UAS which are connected to, or likely to come into contact with, a source of electricity capable of causing an electric shock, together with the cables or other conductors through which electricity is conveyed to such parts, must be properly insulated and mechanically protected so as to prevent the risk of such a shock.
- 3. Under all foreseeable fault conditions, the UAS must provide protection against electrical hazards arising from an electrical power source.
- 4. The UAS must provide adequate protection against fire hazards.
- 5. The UAS must be designed and manufactured in such a way that electric, magnetic and electromagnetic fields and other radiation generated by the equipment are limited to the extent necessary for the intended operation, and the UAS must operate at a safe level in compliance with the generally acknowledged state of the art, taking account of specific EU measures.

6. The UAS must be designed and manufactured in such a way that, if the control system starts malfunctioning or fails due to a failure of the system itself or an external factor, the UAS will not cause a significant hazard.

7. The UAS must be designed and manufactured in such a way that it does not present any health hazards or risk of injury to eyes or skin from lasers, light-emitting diodes (LEDs) or any other type of radiation;

- (e) bear the following label on the UA in a visible manner:



- (f) be placed on the market with clear operational instructions highlighting the risks related to UAS operations;
- (g) include information required to use the UAS in accordance with the applicable regulations on aviation safety, security, privacy and data protection, liability and insurance and the awareness leaflet defined in Appendix I.12.

*Appendix I.4***Product requirements for class 2 UASs**

This Appendix constitutes Community harmonisation legislation within the meaning of Regulation (EC) No 765/2008 and of Decision No 768/2008/EC for class 2 UASs, while the conformity assessment procedure is defined in Annex II Article II.12.

A class 2 UAS shall:

- (a) be made of materials, and shall have performance and physical characteristics, such as to guarantee that, in the event of an impact with a human body, the severity of the injuries that can be inflicted by the UA does not exceed AIS level 4; in any case, the UAS must have a maximum take-off mass (MTOM), including payload, of less than 25 kg;
- (b) in case of a loss of data link, include a reliable and predictable method to recover the UA that reduces the effect on third parties in the air or on the ground;
- (c) be designed to minimise noise emissions;
- (d) be safely controllable without any training courses;
- (e) include the following design features and functions:
  - (1) an 'auto-return home' function;
  - (2) a maximum attainable altitude of 50 m above the ground through performance limitations or an active limitation system;
  - (3) a geofencing system as per Appendix I.6.a;
  - (4) an electronic identification system as per Appendix I.6.c;
  - (5) compliance with the following requirements:

*I. Physical and mechanical properties*

1. The UAS must have the requisite mechanical strength and, where appropriate, stability, to withstand the stresses to which it is subjected during use without breakage or deformation interfering with its safe flight.

*II. Flammability*

1. The UAS must not constitute a dangerous flammable element in its normal operational environment.

2. The UAS must not be explosive or contain elements or substances likely to explode.

*III. Electrical properties*

1. The UAS shall not be powered by electricity of a nominal voltage exceeding 48 volts direct current (DC) or the equivalent alternating current (AC) voltage, and its accessible parts shall not exceed 48 volts DC or the equivalent AC voltage.

Internal voltages shall not exceed 48 volts 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 broken.

2. *Parts of the UAS which are connected to, or likely to come into contact with, a source of electricity capable of causing an electric shock, together with the cables or other conductors through which electricity is conveyed to such parts, must be properly insulated and mechanically protected so as to prevent the risk of such a shock.*

3. Under all foreseeable fault conditions, the UAS must provide protection against electrical hazards arising from an electrical power source.
  4. The UAS must provide adequate protection against fire hazards.
  5. The UAS must be designed and manufactured in such a way that electric, magnetic and electromagnetic fields and other radiation generated by the equipment are limited to the extent necessary for the intended operation, and the UAS must operate at a safe level in compliance with the generally acknowledged state of the art, taking account of specific EU measures.
  6. The UAS must be designed and manufactured in such a way that, if the control system starts malfunctioning or fails due to a failure of the system itself or an outside factor, the UAS does not create a significant hazard.
  7. The UAS must be designed and manufactured in such a way that it does not present any health hazards or risk of injury to eyes or skin from lasers, light-emitting diodes (LEDs) or any other type of radiation;
- (f) be placed on the market with manuals that include an appropriate description of all aspects that affect the safety of flight, and troubleshooting procedures;
  - (g) include information required to use the UAS in accordance with the applicable regulations on aviation safety, security, privacy and data protection, liability and insurance, and the awareness leaflet defined in Appendix I.12;
  - (h) bear the following label on the UA in a visible manner:



*Appendix I.5*

**Product requirements for class 3 UASs**

This Appendix constitutes Community harmonisation legislation within the meaning of Regulation (EC) No 765/2008 and of Decision No 768/2008/EC for class 3 UASs, while the conformity assessment procedure is defined in Annex II Article II.12.

The UAS shall:

- (a) have a maximum take-off mass (MTOM), including payload, of less than 25 kg;
- (b) in case of a loss of data link, include a reliable and predictable method to recover the UA that reduces the effects on third parties in the air or on the ground;
- (c) be designed to minimise noise emissions;
- (d) be designed as far as practicable to avoid single failures resulting in a loss of control, or be equipped with an automatic system ensuring a safe flight termination in case of failures, or be equipped with an impact energy limitation device;
- (e) include the following design features and functions:
  - (1) an 'auto-return home' function;
  - (2) a geofencing system as per Appendix I.6.b;
  - (3) a maximum attainable altitude of 150 m of height from the ground, through performance limitations or an active limitation system;
  - (4) electronic identification as per Appendix I.6.c;
  - (5) compliance with the following requirements:

*I. Physical and mechanical properties*

1. The UAS must have the requisite mechanical strength and, where appropriate, stability, to withstand the stresses to which it is subjected during use without breakage or deformation interfering with its safe flight.

*II. Flammability*

1. The UAS must not constitute a dangerous flammable element in its normal operational environment.

2. The UAS must not be explosive or contain elements or substances likely to explode.

*III. Electrical properties*

1. The UAS shall not be powered by electricity of a nominal voltage exceeding 48 volts direct current (DC) or the equivalent alternating current (AC) voltage, and its accessible parts shall not exceed 48 volts DC or the equivalent AC voltage.

Internal voltages shall not exceed 48 volts 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 broken.

2. Parts of the UAS which are connected to, or likely to come into contact with, a source of electricity capable of causing an electric shock, together with the cables or other conductors through which electricity is conveyed to such parts, must be properly insulated and mechanically protected so as to prevent the risk of such a shock.

3. Under all foreseeable fault conditions, the UAS must provide protection against electrical hazards arising from an electrical power source.
  4. The UAS must provide adequate protection against fire hazards.
  5. The UAS must be designed and manufactured in such a way that electric, magnetic and electromagnetic fields and other radiation generated by the equipment are limited to the extent necessary for the intended operation, and the UAS must operate at a safe level in compliance with the generally acknowledged state of the art, taking account of specific EU measures.
  6. The UAS must be designed and manufactured in such a way that, if the control system starts malfunctioning or fails due to a failure of the system itself or an external factor, the UAS does not create a significant hazard.
  7. The UAS must be designed and manufactured in such a way that it does not present any health hazards or risk of injury to eyes or skin from lasers, light-emitting diodes (LEDs) or any other type of radiation;
- (f) be placed on the market with manuals that include an appropriate description of all aspects that affect the safety of flight, and troubleshooting procedures;
- (g) bear the following label on the UA in a visible manner:



- (h) include information required to use the UAS in accordance with the applicable regulations on aviation safety, security, privacy and data protection, liability and insurance and the awareness leaflet defined in Appendix I.12.



## *Appendix I.6*

### **Product requirements for UAS components**

This Appendix identifies the product requirements for UAS components while the conformity assessment procedure is defined in Annex II Article II.12.

#### **I.6.a Geofencing class 2**

'Geofencing class 2' shall mean a permanent automatic function to limit the access of the UA to airspace areas or volumes provided as geographical limitations based on the UA position and navigation data. The system shall have the following functions and performance according to standards acceptable to EASA so that it:

- (a) provides an interface to update 'geographical limitation' data containing information on restricted and prohibited airspace areas or volumes defined by electronic data;
- (b) automatically prevents the UA from entering any airspace areas or volumes that are limited for the UA operation;
- (c) automatically limits the height above ground to 50 m within accepted tolerances;
- (d) smoothly interacts with the control of the flight without adversely affecting the safety of flight;
- (e) provides sufficient information to the remote pilot when approaching limited areas or when the system engages with the UA flight control system;
- (f) provides information on the status of the system and prevents any operation when the position or navigation data is not valid.

#### **I.6.b Geofencing class 3**

'Geofencing class 3' shall mean a selectable function to limit the access of the UA to airspace areas or volumes provided as geographical limitations based on the UA position and navigation data. The system shall have the following functions and performance according to standards acceptable to EASA so that it:

- (a) provides an interface to update 'geographical limitation' data containing information on restricted and prohibited airspace areas or volumes defined by electronic data;
- (b) automatically prevents the UA from entering any airspace areas or volumes that is limited for the UA operation;
- (c) automatically limits the height above ground to 150 m within accepted tolerances;
- (d) has a selectable option for operators to switch off the automatic function limiting the access to one or more restricted areas ('info mode'), while not affecting the remaining function limiting the access to prohibited areas;
- (e) smoothly interacts with the control of the flight without adversely affecting safety of flight;
- (f) provides sufficient information to the remote pilot when approaching limited areas or when the system engages with the UA flight control system;
- (g) when operating in 'info mode', provides information about the position and movement of the UA relative to geographical limitations and height limitations;

- (h) provides information on the status of the system and prevents any operation when the position or navigation data is not valid.

#### **I.6.c Electronic identification**

'Electronic identification' shall mean a function to identify a UA in flight without direct physical access to that aircraft. The system shall transmit the following data as applicable according to standards acceptable to EASA:

- (a) the registration of the operator,
- (b) the class of the UAS,
- (c) the type of UA operation,
- (d) the status of its geofencing, and
- (e) its position and height.

#### **I.6.d Electronic identification and management**

Where required for the airspace of the operation, a management function according to standards acceptable to EASA should, in addition to the function required under I.6.c, provide functions to:

- (a) transmit information on the intended flight plan and changes to it during operation;
- (b) receive information on the acceptance of flight plans and related authorisations;
- (c) receive information on other manned aircraft or UA operations;
- (d) receive information on temporary restricted and prohibited airspace areas or volumes.

*Appendix I.7***Operational declaration form**

TBD

*[The form shall include the following information:*

- (a) the operator registration number;*
- (b) the name of the accountable manager, or the owner in the case of a private operation;*
- (c) a description of the UAS;*
- (d) a description of the intended use of the UAS (i.e. the concept of operation);*
- (e) a reference to the 'standard scenario' under which the declaration is made;*
- (f) reference(s) to any document requested to be produced under the 'standard scenario';*
- (g) the date(s), or period of time, and location(s) where the operation is intended to be performed.]*

PROTOTYPE

*Appendix I.8*

**Operational authorisation form**

TBD

PROTOTYPE



*Appendix I.9*

**Operational authorisation: Application form**

TBD

*[The form shall include the following information:*

- (a) the operator registration number;*
- (b) a description of the UAS and its performance;*
- (c) a description of the proposed operation of the UAS (i.e. the concept of operation);*
- (d) a reference to the high-risk 'standard scenario' under which the application is made, if applicable;*
- (e) all the documentation required in the 'standard scenario' or a risk assessment as per UAS.SPEC.70;*
- (f) the operational manual as per UAS.SPEC.80;*
- (g) the date(s), or period of time, and location(s) where the operation is intended to be conducted.]*

PROTOTYPE

*Appendix I.10*  
**LUC application form**  
TBD

PROTOTYPE





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*Appendix I.11*  
**Light UA certificate form**  
TBD

PROTOTYPE



*Appendix I.12*

**Awareness leaflet**

TBD

*[This 'awareness leaflet' will raise the attention of the operator about the risks related to UA operations and provide information about the applicable legislation on aviation safety, security, privacy and data protection, liability and insurance. Reference will be made to a website providing additional information.]*

PROTOTYPE

*ANNEX II*

**MAKING AVAILABLE ON THE MARKET**

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## **Section 1 – GENERAL PROVISIONS**

### **Article II.1. Scope**

1. This Annex establishes a regulatory framework for the making available on the Union market of UAS defined in Appendixes I.2 to I.5 as well as UAS components defined in Appendix I.6.
2. At the exception of UAS falling within the scope of Appendixes I.2 to I.5 and placed on the market by the manufacturer in kit ready-to-assemble, home-built UAS do not fall within the scope of this Annex.

### **Article II.2. Definition**

1. UAS or UAS component falling within the scope of Article II.1 shall mean product for the purpose of this Annex.
2. For the purposes of this Annex the following definitions shall apply:
  - a. 'making available on the market' shall mean any supply of a product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge;
  - b. 'manufacturer' shall mean 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;
  - c. 'authorised representative' shall mean any natural or legal person established within the Community 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 Community legislation;
  - d. 'importer' shall mean any natural or legal person established within the Community who places a product from a third country on the Community market;
  - e. 'distributor' shall mean any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market;
  - f. 'economic operators' shall mean the manufacturer, the authorised representative, the importer and the distributor;
  - g. 'technical specification' shall mean a document that prescribes technical requirements to be fulfilled by a product, process or service;
  - h. 'harmonised standard' shall mean a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (10) on the basis of a request made by the Commission in accordance with Article 6 of that Directive;
  - i. 'accreditation' shall mean an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity;

- j. 'national accreditation body' shall mean the sole body in a Member State that performs accreditation with authority derived from the State;
- k. 'conformity assessment' shall mean the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled;
- l. 'conformity assessment body' shall mean a body that performs conformity assessment activities including calibration, testing, certification and inspection;
- m. 'recall' shall mean any measure aimed at achieving the return of a product that has already been made available to the end user;
- n. 'withdrawal' shall mean any measure aimed at preventing a product in the supply chain from being made available on the market;
- o. 'peer evaluation' shall mean a process for the assessment of a national accreditation body by other national accreditation bodies, carried out in accordance with the requirements of this Regulation, and, where applicable, additional sectoral technical specifications;
- p. 'market surveillance' shall mean the activities carried out and measures taken by public authorities to ensure that products comply with the requirements set out in the relevant Community harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection;
- q. 'market surveillance authority' shall mean an authority of a Member State responsible for carrying out market surveillance on its territory;
- r. 'release for free circulation' shall mean the procedure laid down in Article 79 of Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code (11);
- s. 'CE marking' shall mean a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in Community harmonisation legislation providing for its affixing;
- t. 'Community harmonisation legislation' shall mean any Community legislation harmonising the conditions for the marketing of products.

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

Member States shall take appropriate measures to ensure that products falling within the scope of this Annex are made available on the market or put into service only on the condition that they meet the applicable requirements set out in the relevant Appendixes of this Regulation and do not endanger the safety of persons, property or the environment when correctly maintained and used in accordance with the rules defined in this Regulation.

### **Article II.4. Free movement**

Member States shall not impede, for reasons relating to aspects covered by this Regulation, the making available on the market in their territory of products falling within the scope of this Annex.



## **Section 2 - OBLIGATIONS OF ECONOMIC OPERATORS**

### **Article II.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 relevant requirements set out in Appendixes I.2 to I.6 of this Regulation.
2. Manufacturers shall draw up the technical documentation referred to in Article II.16 and carry out the relevant conformity assessment procedure referred to in Article II.12 or have it carried out.
3. Where compliance of the product with the applicable requirements has been demonstrated by that conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking.
4. Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the product has been placed on the market.
5. Manufacturers shall ensure that procedures are in place to ensure that changes in design, characteristics and software of series products do not alter the compliance of the product or that relevant conformity assessment procedure is undertaken.
6. Manufacturers shall also ensure that procedures are in place to ensure that software upgrades taking place after the placing on the market do not alter the compliance of the product.
7. Manufacturers shall ensure that products they have placed on the market bears a type, batch or serial number or other element allowing its 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.
8. Manufacturers shall indicate on the product their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where the size or nature of the product does not allow it, 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 in a language easily understood by end-users and market surveillance authorities.
9. Manufacturers shall ensure that the product they have placed on the market bears the class identification label defined in the related Appendix I.2 to I.5.
10. Manufacturers shall ensure that products placed on the market are accompanied by operational instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. In case of UA or UAS, instructions shall in addition include the information required to use the UA or UAS in accordance with the applicable legislation with regards to aviation safety, privacy and data protection, liability and insurance. The leaflet defined in Appendix I.12 will be included in each package. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.
11. 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.
12. 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 competent national 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.

13. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the UA, equipment to control it remotely or critical component 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 II.6. Obligations of authorised representatives**

1. A manufacturer may, by a written mandate, appoint an authorised representative.
2. The obligations laid down in Article II.5(1) and the obligation to draw up technical documentation laid down in Article II.5(4) 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 competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the product;
  - c. cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by the products covered by the authorised representative's mandate.

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

1. Importers shall place only compliant products on the market.
2. Before placing a product on the market importers shall ensure that the appropriate conformity assessment procedure referred to in Article II.12 has been carried out by the manufacturer and that the product is in conformity with the essential requirements set out in Appendix I.2 to I.6. They shall ensure that the manufacturer has drawn up the technical documentation, that the product bears the CE marking and, in case of UA or UAS, the relevant class identification label and is accompanied by the documents referred to in Article II.5 (11), and that the manufacturer has complied with the requirements set out in Article II.5 (7) and (8).
3. Where an importer considers or has reason to believe that a product is not in conformity with the essential requirements set out in the related Appendix I.2 to I.6, he shall not place the product on the market until it has been brought into conformity. Furthermore, where product presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.
4. Importers shall indicate on the product their name, registered trade name or registered trade mark 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. This includes cases where the size of the product does not allow it, or where importers would have to open the packaging in order to indicate their name

and address on product. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

5. Importers shall ensure that the product is accompanied by operational instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. In case of UA or UAS, instructions shall include the information required to use the UA or UAS in accordance with the applicable legislation with regards to aviation safety, privacy and data protection, liability and insurance. The leaflet defined in Appendix I.12 will be included in each package. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.
6. Importers shall ensure that, while product is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out the related Appendixes II.2 to II.6.
7. 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.
8. Importers who consider or have reason to believe that products which they have placed on the market is 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, importers shall immediately inform the competent national 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.
9. 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.
10. Importers shall, further to a reasoned request from a competent national 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 II.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, in case of UA or UAS, the relevant class identification label, and is accompanied by the documents referred to in Article II.5 (11), and that the manufacturer and the importer have complied with the requirements set out in Article II.5 (7) and (8).
3. Distributors shall ensure that the product is accompanied by operational instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. In case of UA or UAS, instructions shall include the information required to use the UA or UAS in accordance with the applicable legislation with regards to aviation safety, privacy and data protection, liability and insurance. The leaflet defined in

Appendix I.12 will be included in each package. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

4. Where a distributor considers or has reason to believe that a product is not in conformity with the essential requirements set out in the related Appendix I.2 to I.6, 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 market surveillance authorities.
5. Distributors shall ensure that, while a product is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in the related Appendix I.2 to I.6.
6. Distributors who consider or have reason to believe that a product which they have made available on the market is not in conformity with this Regulation 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 competent national 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.
7. Distributors shall, further to a reasoned request from a competent national 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 II.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 he shall be subject to the obligations of the manufacturer under Article II.5, where he places a product on the market under his name or trade mark or modifies the product already placed on the market in such a way that compliance with this Regulation may be affected.

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

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

- (a) any economic operator who has supplied them with a product falling within the scope of this Annex;
- (b) any economic operator to whom they have supplied a product falling within the scope of this Annex.

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 – PRODUCT'S CONFORMITY**

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

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 relevant product's requirements set out in Appendixes I.2 to I.6 covered by those standards or parts thereof.

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

1. The manufacturer shall perform a conformity assessment of the product with a view to establish the class of the product (in case of a UA) and its compliance with the relevant requirements set out in Appendixes I.2 to I.6. The conformity assessment shall take into account all intended and foreseeable operating conditions.
2. In assessing the compliance of the product with the relevant requirements set out in Appendixes I.2, the manufacturer shall use the internal production control set out in Module A of Annex II to Decision No 768/2008/EC (see Appendix II.1); Where, in assessing the compliance of the product with the relevant requirements set out in Appendixes I.2 to I.6, the manufacturer has applied harmonised standards, the references of which have been published in the *Official Journal of the European Union*, covering all requirements for the product he shall use the internal production control set out in Module A of Annex II to Decision No 768/2008/EC (see Appendix II.1);
3. Where, in assessing the compliance of the product with the relevant requirements set out in Appendixes I.2 to I.6, the manufacturer has not applied or has applied only in part harmonised standards the references of which have been published in the *Official Journal of the European Union*, or where such harmonised standards do not exist, the product shall be submitted with regard to those essential requirements to either of the following procedures:
  - a. EU-type examination set out in Module B of Annex II to Decision No 768/2008/EC that is followed by the conformity to type based on internal production control inset out in Module C of Annex II to Decision No 768/2008/EC (see Appendix II.2);
  - b. conformity based on full quality assurance control set out in Module H of Annex II to Decision No 768/2008/EC (see set out in Appendix II.3).

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

1. The EU declaration of conformity referred to in Article II.5 (11) shall, in case of an UA, identify the class of the product and state that the fulfilment of the corresponding requirements set out in Appendix 1.2 to 1.6 has been demonstrated.
2. The EU declaration of conformity shall have the model structure set out in Appendix II.5, shall contain the elements set out in that Appendix and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which product is placed or made available on the market.
3. The simplified EU declaration of conformity referred to in Article II.5 (11) shall contain the elements set out in Appendix II.6 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 relevant requirements laid down in this Regulation.

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

1. Products covered by this Annex and made available on the market shall bear the CE marking and, in case of an UA, the appropriate class identification label.
2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.
3. Member States shall presume that products bearing the CE marking and, for UA, the class identification label, comply with this Regulation.
4. Products not bearing a CE marking, a class identification label (in case of UA) or which do not otherwise comply with this Regulation may be shown and used at trade fairs and exhibitions, provided that they are accompanied by a sign which clearly indicates that they do not comply with this Regulation and that they will not be made available in the Community before being brought into conformity.
5. On account of the nature of the product, the height of the CE marking and UA class identification label affixed to the product may be lower than 5 mm, provided that it remains visible and legible.

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

1. In case of an UA, the class identification label will be affixed on the right of the CE marking and have a similar size.
2. The CE marking and the UA class identification label shall be affixed visibly, legibly and indelibly to the UA, unless that is not possible or not warranted on account of the nature of the UA. The CE marking and the UA class identification label shall also be affixed visibly and legibly to the packaging.
3. The CE marking and the UA class identification label shall be affixed before the product is placed on the market.
4. The CE marking shall be followed by the identification number of the notified body where the conformity assessment procedure set out in Appendix II.2 is applied.  
The identification number of the notified body shall have the same height as the CE marking.  
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.
5. 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.



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## Article II.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 Appendixes I.2 to I.6. It shall, at least, contain the elements set out in Appendix II.4.
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 so doing fails to present sufficient relevant data or means used to ensure compliance of the product with the related requirements set out in Appendixes I.2 to I.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 Appendixes I.2 to I.6.

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## **Section 4 - NOTIFICATION OF CONFORMITY ASSESSMENT BODIES**

### **Article II.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 II.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 Article II.22.
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 II.20. 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 II.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 II.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 II.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 II.2 or II.3 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.

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 set out in Article 3, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of national 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 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 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 Appendixes II.2 and 3 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 II.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 II.21 in so far as the applicable harmonised standards cover those requirements.

#### **Article II.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 II.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 Appendixes II.2 and 3.

#### **Article II.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, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article II.21.
3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article II.21.

#### **Article II.25. Notification procedure**

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article II.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 attestation of competence.
4. Where a notification is not based on an accreditation certificate as referred to in Article II.24(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article II.21.
5. 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 two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used. Only such a body shall be considered a notified body for the purposes of this Regulation.
6. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.

#### **Article II.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 II.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 II.21, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw 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 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 II.28. Challenge of the competence of notified bodies**

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, 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 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 II.29. Operational obligations of notified bodies**

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Appendixes II.2 and 3.
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 so doing 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 relevant product's requirements set out in Appendix I.2 to 6 or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require that 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 UA or UAS 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 II.30. Appeal against decisions of notified bodies**

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

#### **Article II.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 Appendixes II.2 and 3;
  - (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 Appendixes II.2 and 3, provide the other bodies notified under this Regulation carrying out similar conformity assessment activities covering the same categories of UA or UAS with relevant information on issues relating to negative and, on request, positive conformity assessment results.
3. Notified bodies shall fulfil information obligations under Appendixes II.2 and 3.

#### **Article II.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 II.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 sectoral 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 - OBLIGATIONS AND POWERS OF MEMBER STATES**

### **Article II.34. Precautionary principle**

When competent authorities of the Member States take measures as provided for in this Annex, and in particular those referred to in Article II.35, they shall take due account of the precautionary principle.

### **Article II.35. General obligation to organise market surveillance**

Member States shall organise and perform surveillance of the products falling within the scope of this Annex and placed on the Union market in accordance with Articles 15 to 29 of Regulation (EC) No 765/2008.

### **Article II.36. Instructions to the notified body**

1. Market surveillance authorities may request a notified body to provide information relating to any EC-type examination certificate which that body has issued or withdrawn, or which relates to any refusal to issue such a certificate, including the test reports and technical documentation.
2. If a market surveillance authority finds that a product is not in conformity with the related requirements set out in Appendixes I.3 to I.7, it shall, where appropriate, instruct the notified body to withdraw the EC-type examination certificate in respect of that product.

### **Article II.37. 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 covered by this Regulation 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 product concerned covering all relevant 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.  
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 the second subparagraph of 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 relevant essential requirements set out in Article 3; or
  - (b) shortcomings in the harmonised standards referred to in Article 16 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 three months of receipt of the information referred to in the second subparagraph of paragraph 4, 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 II.38. Union safeguard procedure**

1. Where, on completion of the procedure set out in Article II.37 (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 II.37(5) of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

### Article II.39. **Compliant product which presents a risk**

1. Where, having carried out an evaluation under Article II.37 (1), a Member State finds that although 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 II.40. **Formal non-compliance**

1. Without prejudice to Article II.37, 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 II.14 or II.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 Appendixes II.2 or II.3 is applied, has been affixed in violation of Article II.15 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 corresponding product system being made available on the market or ensure that it is withdrawn or recalled from the market.

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**SECTION 6 – FINAL AND TRANSITIONAL PROVISIONS**

**Article II.41. Penalties**

Member States shall lay down rules on 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. Such rules may include criminal penalties for serious infringements.

The penalties provided for shall be effective, proportionate and dissuasive.

**Article II.42. Transitional provisions**

Member States shall not impede, for the aspects covered by this Annex, the making available on the market or putting into service of products covered by this Annex which are in conformity with the relevant Union harmonisation legislation applicable before [date of entry into force of this Regulation] and which was placed on the market before [date of entry into force of this Regulation].

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## Appendix II.1

### CONFORMITY ASSESSMENT MODULE A

#### INTERNAL PRODUCTION CONTROL

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4 of this Appendix, and ensures and declares on his sole responsibility that the product concerned satisfies the requirements set out in the relevant Appendixes I.2 to I.6.

#### 2. Technical documentation

The manufacturer shall establish the technical documentation in accordance with Article II.16 of this Annex.

#### 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 Appendixes I.2 to I.6.

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

4.1. The manufacturer shall affix the CE marking and, when relevant, the UA class identification label in accordance with Articles II.14 and 15 of this Annex to each product falling within the scope of this Annex that satisfies the applicable requirements of this Regulation.

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 UA or UAS has been placed on the market. The EU declaration of conformity shall identify the UA or UAS 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.

## Appendix II.2

### CONFORMITY ASSESSMENT MODULES B AND C

#### EU-TYPE EXAMINATION AND CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL

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 UA or UAS meets the requirements set out in the relevant Appendixes I.2 to 6.
2. EU-type examination shall be carried out by 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, without examination of a specimen (design type).
3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
  - (b) a written declaration that the same application has not been lodged with any other notified body;
  - (c) the technical documentation. The technical documentation shall make it possible to assess the 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 II.16 of this Annex;
  - (d) the supporting evidence for the adequacy of the technical design solution. That supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied or have not been fully applied. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.
4. The notified body shall examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the product.
  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 that apply to the product concerned, the notified body shall issue an EU-type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the product call if relevant, the aspects of the requirements covered by the examination, the conditions (if any) for its validity and the necessary data for identification of the assessed type. The EU-type examination certificate may have one or more annexes attached.

The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of 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 indicate 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 refused, suspended or otherwise restricted.

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

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

#### 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 II.14 and 15 of this Annex to each product that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Regulation.

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.

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## Appendix II.3

### CONFORMITY ASSESSMENT MODULE H

#### CONFORMITY BASED ON FULL QUALITY ASSURANCE

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

#### 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 II.4;
- (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 relevant 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 relevant 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 UA or UAS field and UA or UAS technology concerned, and knowledge of the applicable requirements of this Regulation. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1(b) to verify the manufacturer's ability to identify the applicable requirements of this Regulation and to carry out the necessary examinations with a view to ensuring compliance of the UA or UAS with those requirements.

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

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

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

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

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

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

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

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:

- (a) the quality system documentation;
- (b) the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.;
- (c) the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel, etc.

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may, if necessary, carry out UA or UA system 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 UA class identification label in accordance with Articles II.14 and 15 of this Annex 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 quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

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

## **8. Authorised representative**

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

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## Appendix II.4

### CONTENTS OF TECHNICAL DOCUMENTATION

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

- (a) a general description of the UA or UA system including:
  - 1. photographs or illustrations showing external features, marking and internal layout;
  - 2. versions of software or firmware affecting compliance with essential requirements;
  - 3. user information and installation instructions;
- (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits and other relevant similar elements;
- (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the UA or UA system;
- (d) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements set out in Article 3, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
- (e) copy of the EU declaration of conformity;
- (f) where the conformity assessment module in Annex III has been applied, copy of the EU-type examination certificate and its annexes as delivered by the notified body involved;
- (g) results of design calculations made, examinations carried out, and other relevant similar elements;
- (h) test reports;
- (i) an explanation of the compliance with the requirement of Article 10(2) and of the inclusion or not of information on the packaging in accordance with Article 10(10).

## Appendix II.5

### EU DECLARATION OF CONFORMITY

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

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## Appendix II.6

### **SIMPLIFIED EU DECLARATION OF CONFORMITY**

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

Hereby, [Name of manufacturer] declares that the UA [system] type [designation of type of UA or UA system] is in compliance with Regulation XX/XX/EU.

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

PROTOTYPE

