SELL YOUR DRONES IN EUROPE

CE MARKING OF UAS BEARING A CLASS IDENTIFICATION LABEL (CIL)

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ALTER TECHNOLOGY

1. THE REGULATORY FRAMEWORK:

Key pointsof EASA rules.

COVERPAGE
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Since the publication of the Delegated Regulation 2019/945, on March 12, 2019, until today, the Regulatory Framework for drones has changed very rapidly. The European Union extended its competencies to regulate all Unmanned Aircraft Systems (UAS), which resulted in the creation of a new regulatory framework. From that point, all industry involved in that sector has been witnessing a quick evolution of this normative framework.

In this guide, the key points of all the documents published by EASA are highlighted to identify the requirements that UAS must comply with to be marketed within the European Union Member States and identify the means of compliance and guidelines related to pilot licenses and training centers.

Commission Implementing Regulation (EU) 2019/947: It was published on May 24, 2019 and establishes detailed provisions for the use of RPAS/UAS, as well as for personnel, including remote pilots, and organizations that participate in such operations.

It is important to note that this regulation does not make a distinction between professional and recreational users, so it is also mandatory for UAS users who carry out sports, recreational, competition, and exhibition activities, as well as all kinds of recreational activities in general, to comply with this regulation.

CE MARKING FOR DRONES

✓ **First amendment to the IR 2019/947**

- Commission Implementing Regulation (EU) 2020/639: It was published on May 12, 2020, and is the first amendment to the 2019/947 Implementing Regulation. It modifies it to include two standard operational scenarios, which are to be carried out with CE marked systems of categories 5 and 6 (marked for the specific category). These two scenarios are intended to cover most operations within the specific category and are defined as follows:

- STS-01. VLOS (Visual Line of Sight) over a controlled land area in a populated environment.
- STS-02. BVLOS (Beyond Visual Line of Sight) with airspace observers over a controlled ground area in a sparsely populated environment.

✓ **Second and last amendment to the IR 2019/947**

- Commission Implementing Regulation (EU) 2020/746: It was published on June 4, 2020, and is the second and last amendment to the implementing regulation 2019/947 to date. The modification refers to the postponement of the dates of application of certain measures in the context of the COVID-19 pandemic.

Delegated Regulation (EU) 2019/945: It was published on March 12, 2019, and has been developed in order to establish the requirements for the design andmanufacture of Unmanned Aircraft Systems intended to be used in accordance with the standards and conditions defined in Implementing Regulation (EU) 2019/947.

The type of RPAS/UAS whose design, production, and maintenance will be subject to certification is also defined. Likewise, it establishes the rules relating to the commercialization of these systems intended to be used in the open category and to their free circulation in the European Union. This Regulation also establishes the rules applicable to RPAS/UAS operators from third countries when they carry out operations under Implementing Regulation (EU) 2019/947 within the airspace of the Single European Sky.

✓ **First and the only amendment to the DR 2019/945**

- Delegated Regulation (EU) 2020/1058: It was published on April 27, 2020, and it is the first and only amendment to the Delegated Regulation 2019/945 to date. In addition to the classes previously published (C0 to C4), two new classes of UAS, C5, and C6, are introduced in the specific category.

All these documents were compiled inside a unique edition called **Easy Rules for Unmanned Aircraft Systems (eRules),** published by EASA, to make easier the understanding of the new regulatory framework. This document is a comprehensive, single system for the drafting, sharing, and storing of rules and regulations that are the core of the European Union civil aviation system.

Easy Rules for Unmanned Aircraft Systems (eRules)

- Commission Implementing Regulation (EU) 2019/947- Page 9
- Commission Delegated Regulation (EU) 2019/945 - Page 243

Source: EASA website

It must be pointed out that it is not an official regulatory reference and EASA accepts no liability for damage of any kind resulting from the risks inherent in the use of this document. To check the consolidated texts of the regulations in force please refer to the next links:

- IR 2019/947:

  https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02019R0947-20210805

- DR 2019/945:

  https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02019R0945-20200809

Regulation Overview: Applicable legislation

To establish a clearer view of the entire regulatory framework applicable to all drones, a distinction between two different cases must be done:

1. Rules **applicable when placing the drone on the market**
   a. Several legislations potentially apply to **ALL** drones placed on the market, defined by Chapter II of Regulation 2019/945, such as:

- Radio Equipment Directive (RED. 2014/53/EU)
- Machinery Directive (MD. 2006/42/EC)
- Toy Safety Directive (TSD. 2009/48/EC)

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014L0053
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32006L0042
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32009L0048

2. Rules **applicable to the operation** of the drones

a. To cover more specifically the risks related to the operation of UAS in the Single European Sky airspace, the **EASA Basic Regulation 2018/1139** defines an aviation regulatory framework that defines **three categories of operations** according to their associated risks.

i. For low-risk operations (open category and standard scenarios), no authorization nor risk analysis is required but can only involve drones bearing a class identification label (CIL) and compliant to the requirements defined by Chapter II of Regulation 2019/945. Drones privately built and those included in article 20 (R947) will also be able to fly inside the open category.

ii. For medium-risk operations (specific category), requirements on the UAS are derived from the risk analysis performed according to the SORA methodology; compliance is verified through the operation authorization process (which may include verification by EASA) but is NOT required at the moment of placing the drone on the market.

iii. For high-risk operations, UAS must be certified by EASA.

All drones placed on the market must comply with several directives (in particular, RED and MD), and for UAS bearing a CIL must also comply with the detailed requirements defined by Chapter II of R945.

It should also be noticed that the aviation regulatory framework set by EASABasic Regulation 2018/1139 addresses more specifically the risk related to the operation of the UAS in the SES airspace; the other directives apply to risks other than those associated with the safety of the UAS flight.

2. CE MARKING AND CLASS LABEL FOR DRONES:

All you need to know andunderstand.

2.1. General Aspects

UAS placed on the EU market are subject to different product harmonization legislation (Directives MD, RED, EMC, and others). In addition, UAS placed on the market with a CIL must also comply with the product harmonization legislation defined by Chapter II of R945.

Essential requirements for UAS are defined in Annex IX of the EASA Basic Regulation, and R945 is a Commission Delegated Regulation detailing them.

The Delegated Regulation (EU) 2019/945 "lays down the requirements for the design and manufacture of unmanned aircraft systems ('UAS') intended to be operated under the rules and conditions defined in Implementing Regulation (EU) 2019/947 and of remote identification add-ons." Please also note that R945 only addresses the risks of operations performed in the SES airspace; consequently, it does not apply to products intended only for indoor use.

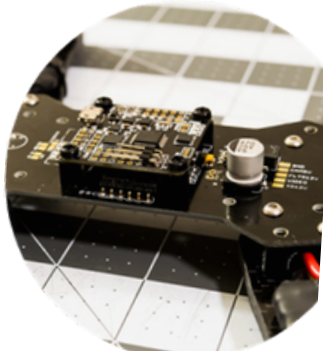
According to Article 4 (R945), "UAS which are not toys within the meaning of Directive 2009/48/EC (Toys Directive) shall comply with the relevant health and safety requirements laid down in Directive 2006/42/EC (European Machinery Directive) only in respect of risks other than those related to the safe flight of UAS," more specifically, risks that are not related to air and ground collisions of the unmanned aircraft while in flight in the Single European Sky airspace, at the exclusion of the protection of persons involved in the operation of the UAS (as indicated in the standardization mandate M/567). In addition, the MD will cover the risks related to all types of machinery that could be included on the UAS (like, for instance, spraying equipment).

- When are products considered toys?

According to the Toys Safety Directive (TSD) 2009/48/EC Article 2, "this Directive shall apply to products designed or intended for use […] by children under 14 years of age."

As Article 9 of It, the R2019/947 indicates, the minimum age for remote pilots operating a UAS in the 'open' and 'specific' category shall be 16 years. However, there are cases, i.e., for privately built UAS with a maximum take-off mass of less than 250g, where no minimum age shall be required, and other cases where the Member state may lower the required age in their territory.

Consequently, one of the necessary conditions that should be complied with to consider a UAS a toy is to have a weight under 250 gr. It would not make sense for a manufacturer to place a toy UAS of more than 250 gr on the market, as the market will not exist or be very limited to a few Member States.



2.2 Obligations of Manufacturers and Importers

Manufacturers play a crucial role in ensuring that products placed on the extended single market of the European Economic Area (EEA) are safe. They are responsible for checking that their products meet EU safety, health, and environmental protection requirements. Furthermore, the manufacturer's responsibility is to carry out the conformity assessment, set up the technical file, issue the EU declaration of conformity, and affix the CE marking to a product. Only then can this product be traded on the EEA market.

On the other hand, importers and distributors help ensure that only products compliant with EU legislation and bearing the CE marking are placed on the extended Single Market of the EEA. As they are the intermediaries between manufacturers and traders, they must have overall knowledge of the legal requirements and ensure that the products they distribute or import meet them.

Regarding manufacturer's and importers' obligations, these Regulations are apparent on this point. To highlight:

- Manufacturers shall draw up the technical documentation and carry out or subcontract the relevant conformity assessment procedure. Where requirements set out in parts 1 to 6 of the annex to Delegated Regulation (EU) 2019/945 have been fulfilled, and conformity assessment has been demonstrated through conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking. This documentation must be kept for 10 years.

- The manufacturer shall ensure that each system has a unique identification number, mainly because of the mandatory remote identification (remote ID).

- Manufacturers shall ensure that the product is accompanied by the required manual and information notice and provide the relevant authority with all documentation relating to the product made available on the market.

- Similarly, it should be noted that importers should ensure that products comply with all relevant requirements to be placed on the market and, if this is not the case, immediately inform the manufacturer of any irregularities detected.

- Likewise, distributors must act with due diligence concerning the requirements set out in the Regulation, verifying the product's relevant CE marking, including the manual, etc.

2.3 Product Compliance

Product compliance is the main concept considered for achieving our system reliability. This part of the process is achieved by complying with a **product conformity assessment.**

Regulation 2019/945 sets out modules for the product conformity assessment procedures, including procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. The manufacturer shall carry out this assessment by one of the following procedures (modules):

- Internal production control (Module A)
- EU type-examination followed by conformity to type based on internal production control (Module B + Module C), or
- Compliance based on total quality assurance (Module H)

More precisely, the conformity assessment of C1, C2 and C3 UAS must be performed either using module B+C or module H that both require the involvement of an NB.

This Declaration of Conformity shall state that compliance of the product with the requirements has been demonstrated with the essential requirements set out all applicable regulations which include R945 for UAS bearing a CIL, specifying its class, which can be from class 0 to 4 for the open category and 5 or 6 for the specific category. This point is fundamental as a very recurrent issue is the definition of acceptable means to demonstrate compliance with these requirements.

In this regard, it is worth noting that these means of compliance are being developed by the ASD-STAN Working Groups, where **Alter Technology participates. This working group is responsible for elaborating the first 4 parts of the new Standard prEN4709 to show compliance with the requirements stated in the Delegated Regulation 2019/945. These parts are:**

- Part 001: Product requirements and verification for the Open category
- Part002: Direct Remote Identification
- Part 003: Geo-awareness requirements
- Part 004: Lighting requirements

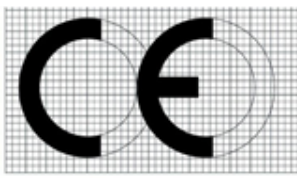
2.3 CE MARKING

The CE marking is the process by which the manufacturer/importer shows users and competent authorities that the marketed equipment complies with the mandatory legislation which includes Regulation 2019/945 for UAS bearing a CIL.

The CE marking shall be visibly, legibly, and indelibly affixed to the product or to the data plate affixed to it. When this is not possible or is not justified due to the size of the product, it will be placed in the packaging.

The indication of the sound power level contemplated in Part 13 to 15 of the Annex of R945, will be affixed, if applicable, in a visible, legible, and indelible manner on the UAS, except when it is not possible or is not justified due to the size of the product, as well as in the packaging.

The CE marking will be followed by the identification number of the notified body when applicable. This point is also fundamental since the concept of Notified Body is introduced for this Delegated Regulation. In the following sections, the responsibilities of the Notified Body and their role in helping and assisting the manufacturer along the certification process are detailed. Finally, it should be noted that the manufacturer shall prepare any technical documentation accompanying the declaration of conformity, which shall contain all relevant data and details of the means used by the manufacturer to ensure compliance of the product with the requirements laid down.



The Notifying Authorities are the ones that shall designate the Notified Bodies in charge of the conformity assessment. These bodies shall, in turn, comply with the following requirements:

- **The conformity assessment body shall be a body independent (third party) of the assessing organization.** A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use, or maintenance of the assessed product, i.e., the whole value chain of a UAS, may be considered as a conformity assessment body under this Regulation, provided that its independence and the absence of any conflict of interest are demonstrated.

- The conformity assessment body, its officers, and the personnel responsible for carrying out the conformity assessment tasks must not carry out any activity related to the product. That is, they shall not be the designer, manufacturer, supplier, purchaser, owner, user, or maintainer of the product, nor the representative of one of those parties, precisely, to preserve the precept of the absence of conflict of interest in this regard.

- At all times, with respect to each conformity assessment procedure and each type or category of products for which it has been notified, **the conformity assessment body must have qualified personnel with sufficient experience** to perform these tasks, as well as, of the procedures that guarantee transparency, distinguishing the tasks performed as a notified body from any other activity.

- Not least, it is worth mentioning that **the staff of the conformity assessment body will observe professional secrecy about all the information collected** in the framework of their tasks. Class Identification Label (CIL) for UAS.

The CIL is affixed on a UAS by the manufacturer because the manufacturer targets this product to a specific market segment corresponding to a certain type of operation. Therefore, the need for the product to comply with a set of requirements defined by R945 can be considered a result of this strategic decision reflected by the affixing of the corresponding CIL on the UAS. In other words, the CIL does not demonstrate compliance to the requirements of R945 but requires this compliance. Compliance is demonstrated by the CE marking.

The UAS class identification label shall be affixed to the drone and its packaging in a visible, legible, and indelible manner and shall be at least 5 mm high. It shall be prohibited to place markings, signs, or inscriptions on a product that may lead to confusion to third parties as to the meaning or form of the class identification label.

It is important to highlight that up to 7 different classes of UAS have been established. Five of them, for the open category(C0to C4) and two more for the specific category (C5 and C6) associated with two standard scenarios, STS-01 and STS-02, developed by the European Authorities. The concept of UAS classes has been developed to enable low risks operations without the need to obtain authorization from the national aviation authority (open category and STS). In consequence, they do not 'facilitate the application for permits' but remove the need for any permit and related safety analysis, only an operational declaration indicating compliance is requested when flying were an STS.

The class is defined by the manufacturer considering the market segment targeted by the product, and, as a result of this selection, some limits to the physical characteristics of the drone and other specifications apply.

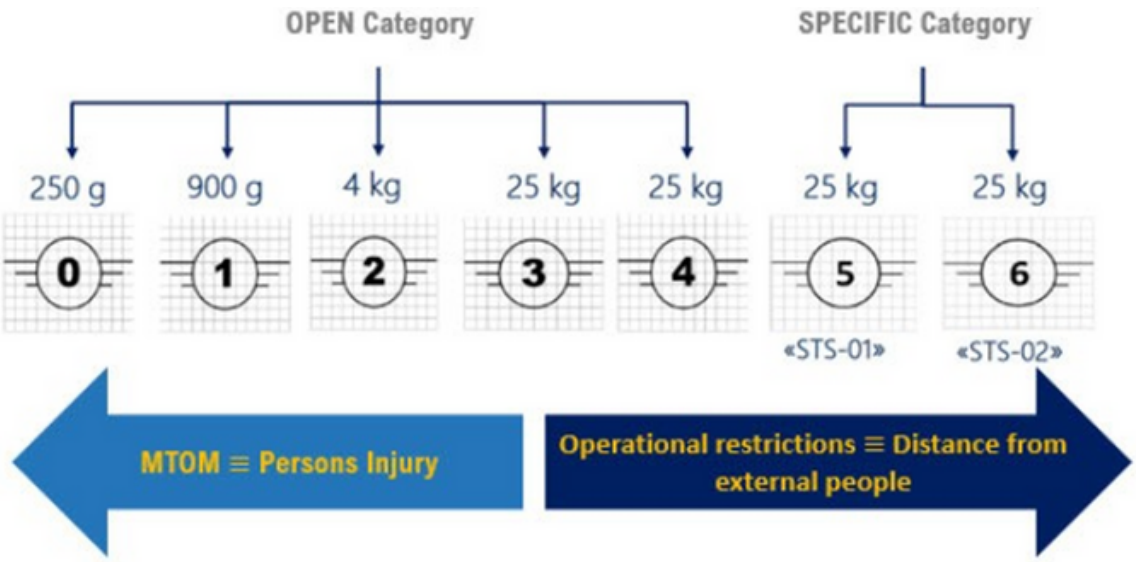


Figure 3: UAS Classes for open and specific category

3. ALTER TECHNOLOGY:

The FIRST NOTIFIED BODY for the DRONES REGULATION 2019/945

In Spain, Notified Bodies must be accredited by ENAC (Entidad Nacional de Acreditación), the national accreditation body. ALTER TECHNOLOGY is a Notified Body for the evaluation of conformity of drones inside the open category (Classes C0 to C4) and is working hard to extend its accreditation to the specific category classes (C5 and C6) in the short term.

ALTER TECHNOLOGY AND THE NOTIFIED BODY (NB) ROLE

The tests that must be followed in the conformity assessment process to ensure that the equipment complies with EN standards must be carried out in an Accredited laboratory. ALTER, as a Notified Body for the Drones Regulation is able to issue an EU-Type examination certificate that reflects that this entity (NB) has verified that the system complies with the regulatory requirements.

It is important to remark that a Notified Body acts as a third party in the evaluation of a product in accordance with the mandatory regulation and issues an opinion on it. In addition to test reports issued by an Accredited Laboratory and depending on the conformity assessment procedure Module applied, it may require periodic audits to verify that the product is still produced in the same manner as the product that has passed the tests included in the standards. This will NOT be required when verification is done through Modules A and C. The Notified Body is the one who issues the EC-type examination certificate that enables the manufacturer to draw up the EU declaration of conformity and allows the manufacturer to sell its product and assures the user that he can use it with the total safety that it correctly complies with the functionality he is looking for.

HOW CAN WE HELP YOU?

In ALTER TECHNOLOGY we are proud to have experts in the drone sector who have been developed the necessary procedures to show compliance with the new regulatory framework in terms of CE Marking, Class Label, and Sound Power Label. They will be able to guide manufacturers or importers in conformity assessment of their drone systems to introduce them safely into the European market.

Currently, we have already started different processes with different manufacturers from many parts of the world: France, Switzerland, Colombia, and Spain. In addition, potential customers have shown interest in our services from faraway countries in Asia and USA.

For these manufacturers (our customers), our capabilities as Notified Body will allow them to sell drones in the E.U and make them more competitive in the drone industry providing a tested and certified product generating confidence to the final user willing to obtain the most advantageous product of the market for their operations.

If you are a manufacturer or importer willing to commercialize your system in Europe, it is time to contact us! You can send us an e-mail to: drones@altertechnology.com and we will guide you in the evaluation of the conformity process of your drone system from the very beginning. We have a lot of years working in certification and regulatory concerns prioritizing our customers' objectives in different markets and sectors.

OUR BEST ADVICE:
DO NOT WAIT UNTIL 2023! YOUR MOMENT IS NOW!

CONTACT OUR TEAM

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