



Certification Program Module B and Module C2

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Subject: Product Certification Program

This document specifies the procedures and rules applied by Aliénor Certification, as a Notified Body, when processing an application for product certification according to Regulation 2016/425 on Personal Protective Equipment.

A certification program generally contains:

- ✓ Requirements to be met by the applicant (product compliance, specific certification rules)
- ✓ Requirements to be met by Certification Bodies

Reference documents:

- ✓ *NF EN ISO/IEC 17065 of 12/2012: Conformity assessment: Requirements for bodies certifying products, processes and services*
- ✓ *NF EN ISO/IEC 17020 of 10/2012: Conformity assessment: Requirements for the operation of different types of inspection bodies*
- ✓ *NF EN ISO/IEC 17025 of 12/2017: Conformity assessment: General requirements for the competence of calibration and testing laboratories*
- ✓ *NF EN ISO/IEC 17021-1 of 09/2015: Conformity assessment – Requirements for bodies carrying out audit and certification of management systems – Part 1: Requirements*
- ✓ *Regulation 2016/425: on personal protective equipment*
- ✓ *CERT CPS REF 28: Specific requirements for accreditation of certification bodies for notification purposes*
- ✓ *Technical file (specific to each type of PPE)*
- ✓ *Certificate of first application*
- ✓ *General Terms and Conditions of Sale for Certification Services*



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| Index | Nature of evolution | Writing | Approval |
|-------|---|--|---|
| A | Preparation of the document | Name: Gaschard M Date: 13/10/2017 | Name: Adalbert A Date: 13/10/2017 |
| B | Modification following audit | Name: Gaschard M Date: 24/09/2018 | Name: Adalbert A Date: 24/09/2018 |
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| D | Clarification of remedies §7 | Name: Gaschard M Date: 02/07/2019 | Name: Adalbert A Date: 02/07/2019 |
| E | Clarification Module B and C2 – Standardization of Appeals Documents | Name: Gaschard M Date: 19/12/2019 | Name: Adalbert A Date: 19/12/2019 |
| F | Module C2 Update | Name: Gaschard M Date: 10/13/2020 | Name: Adalbert A Date: 10/13/2020 |
| G | Applicant Test Report Criteria | Name: Gaschard M Date: 21/05/2021 | Name: Adalbert A Date: 21/05/2021 |
| H | Communicating repository changes | Name: Gaschard M Date: 10/12/2021 | Name: Adalbert A Date: 10/12/2021 |
| I | Addition of Module D requirements + modification of suspension and withdrawal procedures and appeal procedure + addition of reference documents | Name: Gaschard M Date: 05/01/2023 | Name: Adalbert A Date: 05/01/2023 |
| J | Separation of Module B and Module C2 Certification Program + modification of test report validity dates | Name: C.HAMMAMI Date: 12/02/2024 | Name: A.ADALBERT Date: 12/02/2024 |
| K | Procedures for taking into account a test report issued under ISO 17025 accreditation during the EU type-examination procedure + addition of a complaint procedure | Name: C.HAMMAMI Date: 09/10/2025 VISA: SIGNED | Name: P.CUILLERIER Date: 09/10/2025 VISA: SIGNED |



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Aliénor Certification is notified to carry out module B and module C2. Module C2 is reserved for category III PPE.

3. Definitions

PPE: Personal Protective Equipment

Applicant: a legal entity that applies for certification of conformity for a product and undertakes to maintain such compliance. This legal entity is either the manufacturer or its mandated representative in the European Union. Even if a third party (e.g. consultant) submits the request, the manufacturer remains responsible for the conformity of his product.

CE marking: Marking in the prescribed form symbolizing that the product meets the basic requirements for safety and health and thus promoting free trade within the European Union

Harmonised standard: European standard established under the mandate of the European Commission in the European Journal. Harmonised standards indicate a presumption of conformity with basic safety and health requirements

Notified body: an independent accredited institution authorised to carry out tasks (tests, type examination, periodic follow-up checks) within the framework of the relevant standard

EU type-examination: the part of the conformity assessment procedure by which a notified body examines the technical design of PPE and verifies and certifies that it meets the requirements of the Regulation applicable to it.

EU type-examination certificate: declaration by the notified body that the PPE meets the essential safety and health requirements. Applies only to PPE of categories 1 and 2

Declaration of conformity: a statement written by the manufacturer confirming that the PPE meets the essential safety and health requirements. The content of the declaration of conformity varies according to the category of the PPE and the system that applies to it

Evaluation report: report from an approved body (e.g. notified) listing the activities carried out and their results

Module B: EU type-examination: conformity assessment procedure by which a notified body examines the technical design of PPE and verifies and certifies that it meets the requirements of Regulation 2016/425 applicable to it.

Module C2: Conformity to type on the basis of internal control of production and supervised checks of the product at random intervals: periodic inspection carried out by a notified body with the aim of verifying that the PPE continues to meet the essential safety and health



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requirements applicable to it, checking the homogeneity of the production of conformity to the technical file submitted during the EU type-examination

Module D: Type conformity based on quality assurance of the production method: periodic surveillance check carried out by a notified body in the production process of the manufacturer's production site to ensure that the quality system applied in the manufacturer's production site ensures that the PPE conforms to the type described in the EU type-certificate and meets the requirements of Regulation (EU) 2016/425

4. Certification procedures

4.1. Application for certification

If a company wishes to have PPE certified, it contacts Aliénor Certification. This initial phase consists mainly of the exchange of general information on the progress of the procedure. The applicant must provide the following information to Aliénor Certification in order to be able to draw up the quote:

- ✓ Details of the manufacturer or its agent
- ✓ The reference and characteristics of the product (or group of products)
- ✓ The harmonised standard or technical specification according to which they wish to certify
- ✓ The required documents that must be made available to Aliénor Certification: Technical File and certificate of first application

4.2. Application Review and Certification Contract

Following this request, a review of the application is carried out to verify that Aliénor Certification has the means and skills necessary for certification according to Module B and to ensure that the information provided by the applicant is sufficient to establish a certification contract.

If the data provided is deemed sufficient, Aliénor Certification sends the applicant a certification contract (consisting of a quotation accompanied by the certification program and the general terms and conditions of sale for certification services (SUP/ADM-006)) determining the rights and obligations of both parties and including a price offer for the work to be carried out.

If the applicant signs the certification contract, a client file (SUP/QUA-015) is created in which all information related to the application is recorded.

The staff of Aliénor Certification, entering the evaluation phase, checks whether the information in the technical file made available to them by the company is complete. If so, test specimens or additional information in order to complete the file will be requested.



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The applicant provides the necessary documents with identification and description of the products and materials defined, and the deadline for the service, written on the quote, does not start until all these documents are received. The sole purpose of this first check is to verify the entire file, and it does not mean that the technical file or PPE complies with the legal requirements.

4.3. EU Type Examination: Module B

After consultation with the applicant, an EU type-examination is carried out. The technical file is the essential input data for the verification of the essential health and safety requirements of Regulation 2016/425 (Annexes II and III).

The technical details are defined in harmonised standards or other documents when the latter do not exist or are not sufficient to verify the essential requirements, such as coordination documents (French and European interpretation sheets), internal protocol carried out by experts or others.

These tests are carried out in a subcontracted laboratory designated by Aliénor Certification in accordance with the applicable subcontracting rules. These rules are based in particular on the European coordination sheet RFUs n°CNB/PPE-R/00.070 and on accreditation to ISO/IEC 17025 or qualification to the applicable requirements of ISO/IEC 17025. Aliénor Certification assumes full responsibility for the tasks performed by its subcontractors. In cases where the applicant already has test reports, they may only be **accepted if they come from an ISO/IEC 17025 accredited third-party laboratory independent of the manufacturer and the product being tested. Before accepting a test report sent by the manufacturer, Aliénor Certification carries out the following checks:**

- 1- **The independence and impartiality of the issuing laboratory. Proof of this verification is kept in the certification file.**
- 2- **The validity of the laboratory's accreditation as well as the coverage of its scope.**

To be taken into account in the conformity assessment of PPE, the test reports already carried out (whether they were carried out under the direction of Aliénor Certification or by an independent third-party laboratory) must be less than:

- 10 years for PPE Head protection;
- 10 years for PPE Eye and Face Protection;
- 10 years for PPE Noise protection;
- 10 years for PPE, life jackets **and buoyancy aids** ;
- 10 years for PPE;
- 5 years for PPE Motorcycle Protective Clothing;
- 5 years for PPE Protective clothing, hands and arms;
- 5 years for PPE Sports and diving protective clothing



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In all cases, Aliénor Certification is the sole decision-maker on whether or not to accept test reports.

By default, the user manual will be validated in French. In the absence of a user manual in French, the validation will be carried out in English and, in all cases, the applicant is responsible for the translation.

At the end of the EU type-examination, Aliénor Certification writes an evaluation report containing the conclusions of the evaluation.

4.4. Periodic Monitoring for Category 3 PPE: Module C2

As soon as a certificate is awarded and during its period of validity, supervision is exercised by Aliénor Certification which includes:

- Reviewing changes in documents and practices that the manufacturer is required to report to the Manufacturer;
- Periodic checks are carried out on the product to verify that the control of production remains in compliance with the requirements of the standard.

Each year, following the initial certification, Aliénor Certification contacts the certificate holder to carry out a follow-up check in order to verify the conformity of the PPE. The manufacturer can choose between modules C2 and D, but will have to communicate their choice during the type examination by means of mandatory information in the technical file.

If an applicant wishes to entrust the C2 module to Aliénor Certification while the initial EU examination has been carried out in another notified body, Aliénor Certification will contact the latter in the event of difficulties related to the conformity assessment of the sample.

Aliénor Certification carries out the follow-up control module C2 according to 2 axes:

- To comply with paragraph 2A of Coordination Sheet PPE-R/00.007 (Sample Conformity), Aliénor Certification selects an appropriate statistical sample of PPE manufactured at a location agreed upon with the manufacturer. The methods of sampling and the tests carried out will be the subject of a contract review with the manufacturer.

Aliénor Certification will subcontract the tests. In the event that an RFUS exists on the tests to be performed, Aliénor Certification will base itself on the latter; otherwise, Aliénor Certification will define and apply the critical tests of the standard. However, the leaflet and markings will be checked at each check. These tests are carried out in a subcontracted laboratory designated by Aliénor Certification in accordance with the same procedures as those defined in § 4.3 of this document.



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- In order to comply with paragraph 2B of the coordination sheet PPE-R/00.007 (homogeneity of production), a representative of Aliénor Certification will carry out a control of the homogeneity of production. This control will consist of an audit of the means of control of production as well as verifications of the design and documentation (instructions and markings) of the PPE.

After the audit has been finalized, Aliénor Certification draws up a module C2 evaluation report and a decision summarizing the conclusions of the latter. This report determines whether the PPE still complies with the requirements of the standard and whether it corresponds to the model offered at the time of the type examination. In the event of non-compliant tests, Aliénor Certification will inform the client in accordance with Rfu PPE-R/00.009 (Horizontal group).

In the event that it is impossible to collect (lack of stock, reference not yet produced), Aliénor Certification will send the customer a letter of suspension, in the form of a registered letter with acknowledgement of receipt, with the reasons for the suspension. For the customer, this letter represents the prohibition of placing the product on the market from the day of receipt until the situation is regularized.

4.5. Handling non-conformities

In the event of non-compliance or missing information regarding the EU type-examination, the business manager in charge of the case will ask the client to take the appropriate corrective measures and/or provide the necessary elements to carry out the EU-type examination. If the client does not respond within 3 months, the case will be closed.

4.6. Certification decision

After reviewing the evaluation report and the results of the EU type-examination or the Module C2 check, the certification manager shall make one of the following decisions:

- Granting Module B certification or Module C2 certificate if the PPE complies with the applicable essential health and safety requirements. In this case, the certification manager signs the review and decision form. Then, the President of Aliénor Certification signs the EU type certificate.
- Refusal of Module B or Module C2 certification if it is not possible to demonstrate compliance of the PPE. In this case, the certification manager signs a review and decision form (negative) and informs the President of Aliénor Certification and the applicant. Aliénor Certification will then make a proposal for the refusal of an EU type certificate.



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The EU type-examination certificate will include:

- The initial validity start date of the certificate
- The expiry date of the certificate (5 years after the date of issue)
- The date on which the certificate was renewed

The placing on the market of a Category III product is subject to the presence of an EU type examination certificate (Module B) and a Module C2 or D certificate

4.7. Review of the EU-type examination certificate

The review of the EU-type examination certificate shall be set at 5 years after the date on which the certificate starts to be valid. The certificate will be re-examined in 2 cases:

- *Expiry of the validity date of the certificate:* without any change in type or technical development. In this case, an administrative re-certification (simplified procedure) will be carried out (without testing). The manufacturer must apply 12 to 6 months before the end of the validity of the certificate.
- *Evolution of the state of the art and/or modification of the type:* Aliénor Certification will carry out a re-certification, identical to a module B certification, with technical tests according to the needs to validate the change(s). At the time of the review of the test reports, the periods of validity indicated above (see 4.3 of this document) do not apply to test reports not affected by the change which gave rise to the request for review.

Aliénor Certification shall ensure that the review procedure is finalised before the expiry date of the EU-type examination certificate in accordance with point 4.2 of Annex VII to Regulation 2016/425.

4.8. Changing the repository

Aliénor Certification will inform the applicant of any changes that may impact the certification of their product.

5. Manufacturer's obligations

Each applicant is presumed to comply with the General Terms and Conditions of Sale and the provisions of the contract, between Aliénor Certification and the manufacturer, which was concluded at the beginning of the certification procedure.

In addition, the applicant is expected to comply with the requirements of Regulation 2016/425 on personal protective equipment.



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The manufacturer undertakes:

- to make available to Aliénor Certification or its representative: all the information and documents necessary, in paper or electronic form, to demonstrate the compliance of the PPE with these regulations;
- to accept the application of the financial regime;
- to notify Aliénor Certification of any change made to the production control system as described in the file submitted to Aliénor Certification and likely to call into question the validity, content or scope of the certificate, such as:
 - ✓ a change of name,
 - ✓ a change of laboratory,
 - ✓ a change in the production process,
 - ✓ the addition or removal of production sites,
 - ✓ modification of normative references,

6. Penalties for an offence

In the event of a statement of offence or defect, Aliénor Certification reserves the right to take measures to sanction the manufacturer. The sanctions that may be imposed on a manufacturer who does not comply with its obligations (see 5 above) may be based on the seriousness, suspension or withdrawal of the certificate(s). These sanctions, taken by the authorised person of Aliénor Certification, are preceded by a warning accompanied by a formal notice to put an end to the non-conformity(s) observed within 15 days.

In the event of an unjustified refusal to pay an invoice, the suspension procedure is systematically implemented.

Aliénor Certification assesses the seriousness of the offence and takes sanctions accordingly.

In accordance with the regulations, the suspension or withdrawal of a certificate of conformity results in a ban on the placing on the market of the PPE concerned.

The procedure for "Withdrawal or Suspension of certification" can be consulted on the Aliénor Certification website.



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6.1. Suspension:

The process of temporarily invalidating an EU type-certificate for all or part of its scope.

When Aliénor Certification finds that a holder of an EU type-examination certificate no longer meets the requirements of the regulation, it may decide to suspend all or part of the certificate. **The suspension may occur following the following observations:**

- **Failure to comply with contractually defined requirements relating to certification,**
- **Failure to comply with the provisions set out in the surveillance procedure,**
- **Deviations from the specific requirements set out in the certification,**
- **Failure to comply with regulatory requirements by certification,**
- **Following the outcome of the processing of a complaint.**
- **Misuse of the certification mark**

This may result from the review of an annual monitoring report, following a complaint or from any other source.

At that time, the organization owning the certified product must cease to avail itself of its certification and remove any communication relating to the certification of Aliénor Certification subject to the suspension. Otherwise, failure to comply with these requirements will result in an outright withdrawal.

To lift a suspension and reinstate a certificate, the customer has the option to take corrective action and/or carry out additional tests within 6 months of the suspension decision. These will be sent to Aliénor Certification for evaluation.

In the event of no response to lift the suspension, Aliénor Certification will withdraw the certificate.

6.2. Withdrawal:

The withdrawal procedure is systematically implemented:

- In the case of misuse of the certificate of compliance
- If requests for corrective action are not followed up after the deadline set.
- If the issues that led to the suspension of certification have not been resolved within the deadlines set by Aliénor Certification

Any final withdrawal is the subject of information to all the ministries concerned. The certificate must be returned to the notified body or destroyed. The withdrawal of the certificate prohibits any reference to the certification concerned.



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A withdrawal of the certificate cannot be lifted, the applicant will have to be the subject of a new application for his product.

7. Complaints and appeals procedure

7.1. Appeals

The applicant has the right to appeal against a certification decision of Aliénor Certification. This must be done in writing and must be addressed to the President of Aliénor Certification. The "Complaints and Appeals" procedure can be consulted on the Aliénor Certification website.

In order to be admissible, the appeal must be reasoned and relate to the decision taken by Aliénor Certification.

The applicant has a period of 15 days from the notification of the decision to refuse, reduce, suspend or withdraw his certificate to file the appeal.

Aliénor Certification informs the applicant of the admissibility or otherwise of their appeal and the time needed to process the request. Admissibility is in no way linked to the legitimacy of the reasoning.

- ✓ If the appeal is declared inadmissible, the President of Aliénor Certification informs the parties concerned in writing of the reasons for this declaration of inadmissibility.
- ✓ If the appeal is declared admissible, the President of Aliénor Certification convenes an appeal committee. The appeal committee is composed of 2 project managers and a certification manager who were not involved in the initial decision and who were not involved in the certification file against which the appeal was filed. The manufacturer who filed the appeal has the opportunity to explain and defend their case at the meeting of the Exceptional Impartiality Committee.

The appeal committee issues a favourable or unfavourable opinion and takes the decision by one of its members who has the necessary skills to take the decision. The Appeal Committee's decision is communicated in writing to all parties involved is final, no appeal is possible.

The organization is notified by letter or email of the decision on the appeal within 15 business days of receiving it.

Regardless of the decision of the Appeal Committee, the manufacturer may not claim damages from Aliénor Certification for any damages incurred.



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7.2. Complaints

Complaints can be made orally (by phone) or in writing (email and letter). A written acknowledgement of receipt of the complaint will be sent to the complainant within five business days of receipt.

Subsequently, the applicant is informed of the admissibility or otherwise of the complaint and the time taken to process the file. Admissibility will be based on the relevance of the claim to Aliénor Certification's certification activities and is in no way linked to the legitimacy of the motivation.

The complaint must be analyzed by a person who is not involved in the certification file that was the subject of the complaint.

The organization is notified by letter or email of the decision on the complaint within 15 business days of receipt.

8. Confidentiality

Aliénor Certification will treat all information related to the application with the utmost confidentiality and will not communicate it to third parties without the express consent of the applicant. This does not apply to information which, in accordance with the legislation, must be communicated to surveillance authorities or other notified bodies, such as decisions to refuse, reduce, withdraw or suspend certification. The customer is informed in advance of the information that will be provided, unless prohibited by law.

9. Impartiality

Aliénor Certification has taken all necessary measures to ensure the impartiality of decisions relating to certification. This impartiality is monitored by the mechanism for the preservation of impartiality, which meets at regular intervals. Manufacturers, consumers, authorities and experts are represented by the members of this mechanism for the preservation of impartiality. The terms and conditions of this impartiality system are detailed in Aliénor Certification's quality manual.

10. Abuse

The use of the CE mark with the reference to Aliénor Certification as well as its notified body number for PPE without the issuance of an Aliénor Certification **certificate** is considered to be misuse.