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 in accordance with Regulation 2016/425 on Personal Protective Equipment.

A certification program typically contains:

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

Reference Documents:

- ✓ *Standard NF EN ISO/IEC 17065 de 12/2012*: Conformity assessment: Requirements for bodies certifying products, processes and services
- ✓ *Standard NF EN ISO/IEC 17020 de 10/2012*: Conformity assessment: Requirements for the operation of different types of inspection bodies
- ✓ *standard NF EN ISO/IEC 17025 of 12/2017*: Conformity assessment: General requirements for the competence of testing and calibration laboratories
- ✓ *Standard NF EN ISO/IEC 17021-1 of 09/2015: Conformity assessment – Requirements for bodies carrying out the 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
H	Communicating Repository Changes	Last 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	Last 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 VISA: **SIGNED**	Name: A.ADALBERT Date: 12/02/2024 VISA: **SIGNED**

Responsable Qualité et Responsable Certification
Quality Manager and Certification Manager

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1. Introduction

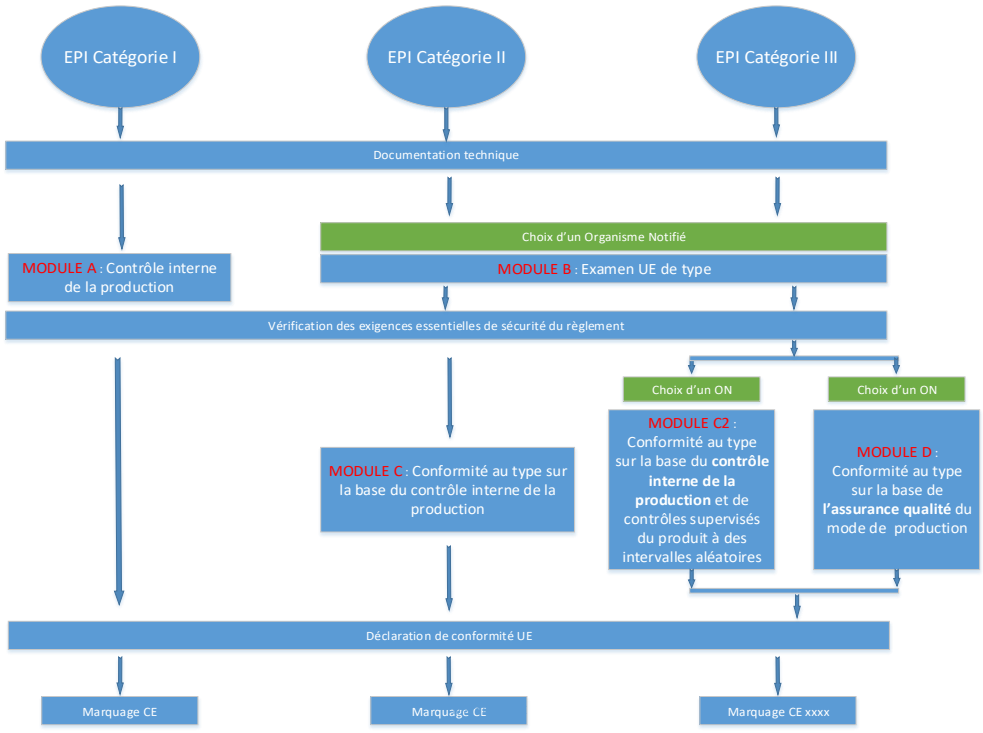
Regulation 2016/425 on Personal Protective Equipment (hereinafter referred to as PPE) states that CE marking is mandatory for PPE. By means of the CE marking, the manufacturer certifies that the product complies with the basic and legal requirements that apply in the field of safety and health and that the product is introduced into the market in accordance with the legislation. The technical requirements that the products must meet are described in the corresponding harmonized European standards and other French and/or European recommendation sheets.

The purpose of product certification is to check the conformity of PPE with the provisions of Regulation 2016/425 in the design phase or in the production phase and to certify this conformity.

2. Scope of application

This document specifies the operating conditions for the certification of Personal Protective Equipment (PPE) associated with the CE marking. The different PPE concerned are defined and specified by the harmonized standards.

Below is the diagram explaining the certification procedure depending on the category of PPE.



Aliénor Certification is notified to complete module B, module C2. Modules C2 is reserved for Category III PPE.

3. Definitions

PPE: Personal Protective Equipment

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

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

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

Notified body: an independent accredited institution authorized to carry out tasks (tests, type examination, periodic follow-up control) 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: a declaration from the notified body that the PPE meets the essential health and safety requirements. This only applies to Category 1 and 2 PPE

Declaration of Conformity: A declaration made by the manufacturer confirming that the PPE meets the essential safety and health requirements. The content of the declaration of conformity varies depending on the category of PPE and the system applied to it

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

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

Module C2: Conformity to type based on internal production control and supervised checks of the product at random intervals: periodic inspection carried out by a notified body for the purpose of verifying that the PPE continues to meet the essential safety and health requirements applicable to it, by checking the homogeneity of the production and the conformity of the PPE to the technical file submitted during the EU type-examination

Module D: Type conformity on the basis of quality assurance of the mode of production: periodic surveillance check carried out by a notified body in the BU to ensure that the quality system applied at 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 client must provide the following information to Aliénor Certification in order to be able to draw up the quote**:

- ✓ Details of the manufacturer or their authorized representative
- ✓ The **reference and characteristics of the** product (or product group)
- ✓ **The harmonized standard or technical specification according to which it wishes to certify**
- ✓ The required documents that must be made available to Aliénor Certification: Technical file and Certificate of first application

4.2. Review of the application and certification contract

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

If the data provided is deemed sufficient, Aliénor Certification sends the client 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 client 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.

The applicant provides the necessary documents with identification and description of the products and materials defined, the period of service, indicated on the estimate, does not start until all these documents are received. The sole purpose of this first check is to verify the completeness of the file and does not imply that the technical file or PPE complies with the legal requirements.

In order to comply with Coordination Sheet PPE-R/00.050 (Evaluation of module C2 or D, EU type-examination certificate), the notified body carrying out the EU-type examination for a category III product must verify that the evaluation of module D or C2 is present or in progress.

4.3. EU Examination Type: Module B

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

The technical details are defined in harmonized standards or other documents when these are non-existent or insufficient to verify the essential requirements, such as coordination documents (French and European interpretation sheets), internal protocol carried out by expert 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/P/00.006 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 customer already has test reports, they may be used as long as they come from ISO/IEC 17025:2017 accredited testing laboratories and have been carried out within the last few years:**

- **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;**
- **10 years for anti-fall PPE;**
- **5 years for PPE Motorcycle Protective Clothing;**
- **5 years for PPE Protective clothing, hand and arm;**
- **5 years for PPE Sports & Diving Protective Clothing**

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

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

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

4.4. Periodic Monitoring for Category 3 PPE: Module C2

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

Review of changes in documents and practices that the manufacturer is required to report to Aliénor Certification ;

Carrying out periodic checks on the product to ensure that production control remains in line 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 compliance of the PPE. The manufacturer may choose between modules C2 or D, but will have to communicate his choice during the type examination by mandatory information in the technical file.

If a client 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 Compliance), Aliénor Certification selects an appropriate statistical sample of PPE manufactured in a location agreed upon with the manufacturer. The sampling methods and the tests carried out will be subject to a contract review with the manufacturer.

Aliénor Certification will subcontract the tests. In the event that an RFU (Recommendation For Use) exists on the tests to be carried out, Aliénor Certification will base itself on it, otherwise Aliénor Certification will define and apply the critical tests of the standard. However, the leaflet and markings will be checked at each inspection. These tests are carried out in a subcontracted laboratory designated by Aliénor

Certification according to the same procedures as those defined in § 4.2 of this document.

- 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 the production as well as the design and documentary checks (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. Dealing with 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.

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. Re-examination of the EU-type examination certificate

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

- *Expiry of the validity date of the certificate* : without any change in the type or evolution of the technique. In this case, an administrative re-certification (simplified procedure) will be carried out (without testing). The manufacturer must submit the application 12 to 6 months before the end of the validity of the certificate.

- *Evolution of the technique 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 review of test reports, the validity periods 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 finalized 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 customer of any changes that may have an impact on the certification of its 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.

The manufacturer undertakes:

- to keep available to Aliénor Certification or its representative: all the information and documents necessary, on paper or electronically, to demonstrate the compliance of the PPE with this regulation;
- 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 deletion of production sites,
  - ✓ modification of normative references,

6. Penalties for an offence

In the event of a finding of offence or defect, Aliénor Certification reserves the right to take measures to sanction the manufacturer. The penalties that may be imposed on a manufacturer who fails to comply with his obligations (see 5 above) may be, depending on the seriousness, suspension or withdrawal of the certificate(s). These sanctions, taken by Aliénor Certification's authorized person, are preceded by a warning accompanied by a formal notice to put an end to the non-conformity(s) found 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 the necessary sanctions.

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.

6.1. Suspension:

The process of provisionally 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. This may be the result of a review of an annual monitoring report, a claim, or any other source.

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 a lack of response to lift the suspension, Aliénor Certification will withdraw the certificate.

6.2. Withdrawal:

The withdrawal procedure is systematically implemented:

- in the event of misuse of the certificate of conformity
- in the absence of action to be followed up on requests for corrective action after the set deadline.
- **If the issues that led to the suspension of certification have not been resolved within the timeframe set by Aliénor Assurance**

All permanent withdrawals shall be informed 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 relevant certification.

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

7. Appeals Procedure

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 is available 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 client has 15 days from the notification of the decision of refusal, reduction, suspension or withdrawal of his certificate to make the appeal.

Aliénor Certification informs the client of the admissibility or otherwise of the appeal and the time required to process the request within 15 days of receiving the appeal. Admissibility is in no way linked to the legitimacy of the statement of reasons.

An exceptional impartiality committee is scheduled upon receipt of an appeal. It shall rule on its admissibility.

- ✓ 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 people, indicated by the President of Aliénor Certification 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 his case at the meeting of the Exceptional Impartiality Committee.

The appeal committee reviews the case and decides whether to uphold or vary the certification decision. This is communicated in writing to all parties involved. The decision of the appeal committee is final, no appeal is possible.

Regardless of the decision of the exceptional impartiality committee, the manufacturer cannot claim damages from Aliénor Certification for any damages incurred.

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 Assurance has taken all necessary measures to ensure the impartiality of certification decisions. This impartiality is monitored by the Impartiality Preservation Mechanism, 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 marking with reference to Aliénor Certification and its notified body number for PPE without issuing an EU type-examination certificate from Aliénor Certification is considered to be misuse.