



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
C	Modification continued Arrangement preservation Impartiality	Name: Gaschard M Date: 05/12/2018	Name: Adalbert A Date: 05/12/2018

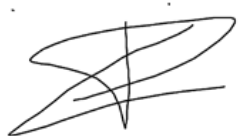


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D	Clarification of remedies §7	Name: Gaschard M Date: 02/07/2019	Name: Adalbert A Date: 02/07/2019
E	Clarification Module B and C2 – Standardization of Appeals Documents	Name: Gaschard M Date: 19/12/2019	Name: Adalbert A Date: 19/12/2019
F	Module C2 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	Name: P.CUILLERIER Date: 09/10/2025
L	Addition of definitions for complaints and appeals; addition of the review procedures for cases involving additional certificates; complaints and appeals; certification restrictions	Name: C.HAMMAMI Date: 16/09/2026 VISA: SIGNED  Chaima HAMMAMI 2026.09.16 14:59:50 +02'00'	Name: P.CUILLERIER Date: 16/09/2026 VISA: SIGNED 



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1. Introduction

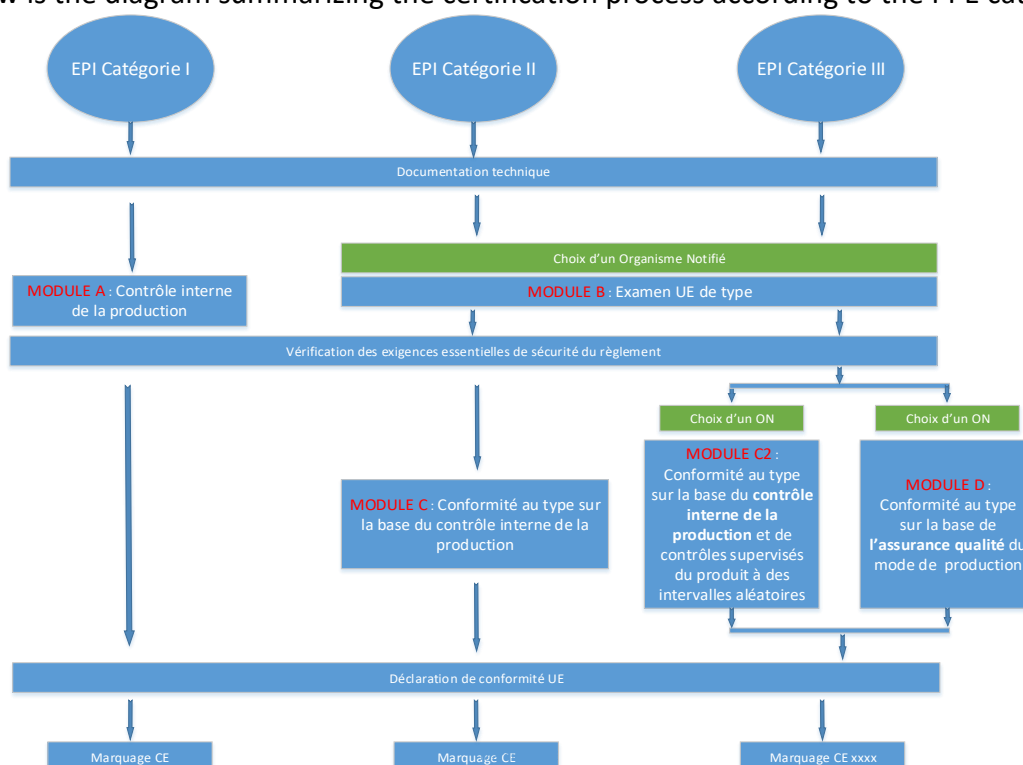
Regulation 2016/425 on Personal Protective Equipment (hereinafter referred to as PPE) states that CE marking is mandatory for PPE. With the CE marking, the manufacturer certifies that the product meets the basic and legal requirements that apply in the field of safety and health and that the product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

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

2. Application

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

Below is the diagram summarizing the certification process according to the PPE category.





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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

Complaint: expression of dissatisfaction, other than an appeal, made by a legal or natural person to a conformity assessment body or an accreditation body, relating to the activities of that body, for which a response is expected.

Appeal: request made by the provider of the conformity assessment object to the conformity assessment body or the accreditation body for that body to reconsider a decision it has already made relating to that object.

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))



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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.

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.



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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 against fall from height;
- 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

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:



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- 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.

- 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).

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 **with the required elements** within 2 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.



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- 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. Review of the EU-type examination certificate

The EU-type examination certificate is issued for a maximum period of five years.

The certificate shall be subject to review:

- before the expiry of its period of validity;
- in the event of developments in the state of the art that may call into question the conformity of the certified type;
- when the manufacturer declares a modification to the certified type that may affect its conformity or the conditions of validity of the certificate.

Depending on the reason for the review and its conclusions, the review may result in:

- the issuance of an addition to the initial certificate
- the renewal of the certificate for a further maximum period of five years;
- or an unfavourable decision where conformity of the type has not been demonstrated.

4.7.1. Addition to the initial certificate:

During the period of validity of the EU-type examination certificate, the manufacturer shall inform Aliénor Certification of any modification to the certified type that may affect its conformity with the applicable essential health and safety requirements or the conditions of validity of the certificate.

Aliénor Certification shall review the information provided and determine the applicable course of action depending on the nature of the request.



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The issuance of an addition to the initial certificate is only possible if the modifications made do not alter the intended purpose or use of the PPE. Aliénor Certification shall assess, on a case-by-case basis, the impact of the modifications on the identity of the certified type and on its conformity with the applicable requirements. Where the modifications result in the PPE being considered a new type, the request cannot be processed by means of an addition to the initial certificate and shall be subject to a new full EU-type examination procedure in accordance with Module B.

Two types of addition to the initial certificate are possible:

➤ Addition to the initial certificate without additional testing:

Where the modification to the type requires approval, but the available information is sufficient to demonstrate the conformity of the PPE without further testing, Aliénor Certification shall carry out a documentary review.

This review shall include, in particular:

- the description and justification of the modification;
- the updated parts of the technical documentation.

Where the conformity of the modified type is demonstrated, Aliénor Certification shall issue an addition to the EU-type examination certificate. This addition shall retain the expiry date of the certificate to which it relates.

➤ Addition to the initial certificate with additional testing:

Where the modification is likely to affect the performance of the approved PPE or its conformity with the applicable requirements, Aliénor Certification shall determine the additional examinations and tests required.

The verifications shall be limited to the characteristics and requirements likely to be affected by the modification. Previous test reports that are not affected by the modification may be retained, subject to their relevance and provided that there have been no developments in the state of the art that would call their conclusions into question.

Where the results confirm the conformity of the modified type, Aliénor Certification shall issue an addition to the initial EU-type examination certificate. This addition shall retain the expiry date of the certificate to which it relates.



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4.7.2. Renewal of the European Type Examination Certificate :

The renewal application shall be submitted to Aliénor Certification no earlier than 1 year and no later than 6 months before the expiry date of the EU-type examination certificate.

This application shall include any changes to the technical documentation or to the PPE declared by the client, the applicable state of the art and, for Category III PPE, a valid Module C2 or Module D certificate.

Two renewal procedures are possible:

➤ Renewal under a simplified procedure:

The simplified procedure may be applied where:

- no unapproved modifications have been made to the type or to its technical documentation;
- no developments in the state of the art (harmonised standard or other technical specification) call into question its conformity.

Aliénor Certification shall then carry out a review. No additional testing shall be required, unless the review identifies an element that may affect the conformity of the type.

Where the conclusions of the review are favourable, the certificate shall be renewed for a maximum period of five years.

➤ Renewal requiring additional examinations or testing:

The simplified procedure cannot be applied where the review identifies, in particular:

- a development in the state of the art (harmonised standard or other technical specification) that may affect the conformity of the PPE;
- a modification to the type that has not yet been approved

Aliénor Certification shall then determine the additional examinations and tests required. These shall be proportionate to the changes identified and to the requirements that may be affected.

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 (renewal) 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, **provided that the application has been submitted within the deadlines specified above.**



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Aliénor Certification does not renew an EU-type examination certificate issued by another notified body. In such cases, a new full EU-type examination procedure in accordance with Module B may be proposed upon expiry of the existing certificate.

Following a review resulting in the issuance of an addition to the initial certificate or a renewed certificate, the certificate holder shall ensure that any superseded version is no longer used. The certificate holder shall either destroy it or clearly identify and archive it in such a way as to prevent any unintentional use.

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.

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,



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6. Restriction, suspension, termination or withdrawal of certification

Where Aliénor Certification identifies a situation that may affect the validity or maintenance of the certification, it shall assess its nature and severity and take the appropriate measures. These measures may include, in particular, restricting the scope of the certification, suspending the certification, terminating it (at the client's request), or withdrawing it.

Such measures may, in particular, result from non-compliance with the applicable requirements, failure to comply with contractual or financial obligations, misuse of the certificate or certification mark, failure to implement the required corrective actions, refusal to undergo an inspection, or any other situation covered by procedure PRO-010 "Withdrawal or Suspension of Certification".

The grounds that may lead to such measures, the decision-making process, any applicable time limits granted, the conditions for reinstatement, and the obligations of the certificate holder are defined in procedure PRO-010 "Withdrawal or Suspension of Certification", available on the Aliénor Certification website at the following address:

[Aliénor Certification – Resources](#)

Depending on the nature and severity of the situation, Aliénor Certification may formally require the certificate holder to take the necessary actions within a specified period. However, where immediate action is necessary, in particular to protect the health or safety of users, a restriction, suspension or withdrawal measure may be imposed without prior formal notice.

Any decision shall be taken by a duly authorised person and notified to the certificate holder. The certificate holder shall comply with the measures and obligations notified to it and may no longer claim the certificate beyond the limits resulting from the decision. The certificate holder shall also remove any communication relating to Aliénor Certification's certificate that is subject to restriction, suspension, termination or withdrawal.

In the event of an unjustified refusal to pay an invoice that has fallen due, Aliénor Certification may initiate the suspension procedure in accordance with the applicable contractual provisions.

7. Complaints and appeals procedure

The applicant has the right to appeal against a certification decision made by Aliénor Certification. Furthermore, Aliénor undertakes to handle any complaint, other than an appeal, submitted by any legal entity or individual.

The procedures for handling complaints and appeals are defined in procedure PRO-007, "Complaints and Appeals", available on the Aliénor Certification website at the following link:

<https://alienor-certification.fr/ressources/>



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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 is considered to be misuse.