OBJECT:

Certification program for products:

This document intends to describe the procedures and rules applied by ALIENOR CERTIFICATION Ltd, as an approved body, for an application for certification of products according to the (Regulation (EU) 2016/425 as brought into UK law and amended) and the Personal Protective Equipment (Enforcement) Regulations 2018 as it applies to the GB Market.

A certification program contains essentially:

- ✓ Requirements that must be followed by the customer (conformity of products, specific rules of certification)
- ✓ Requirements that must be followed by certification bodies

UPSTREAM REFERENCE DOCUMENT:

- ✓ *Standard ISO/IEC 17065*: Conformity assessment – Requirements for bodies certifying products, processes, and services
- ✓ *Standard ISO/IEC 17020*: Conformity assessment - Requirements for the operation of various types of bodies performing inspection
- ✓ *Standard ISO/IEC 17025*: General requirements for the competence of testing and calibration laboratories
- ✓ *(Regulation (EU) 2016/425 as brought into UK law and amended) and the Personal Protective Equipment (Enforcement) Regulations 2018 as it applies to the GB Market.*

Index	Nature of evolution	Editorial	Approval
B	Modification	Name: D. MORALES Date: 06/07/2022	Name: A. ADALBERT Date:06/07/2022
C	Add information about non-discriminatory conditions in §4.1	Name: D. MORALES Date: 02/08/2022	Name: A. ADALBERT Date:02/08/2022
D	Update of certification procedures	Name: D. MORALES Date: 5/10/2022	Name: A. ADALBERT Date: 6/10/2022
E	Improvement of the wording of the document. New subtitles and description of §4.2 Initial Control and Application Review, §4.7 Changes affecting certification Description of §4.4 Evaluation Review	Name: D. MORALES Date: 17/05/2023 VISA: **SIGNED** Digitally signed by Diana MORALES Date: 2023.05.17 16:16:56 +01'00'	Name: A. ADALBERT Date: 17/05/2023 VISA: **SIGNED**

SUMMARY

1 Introduction

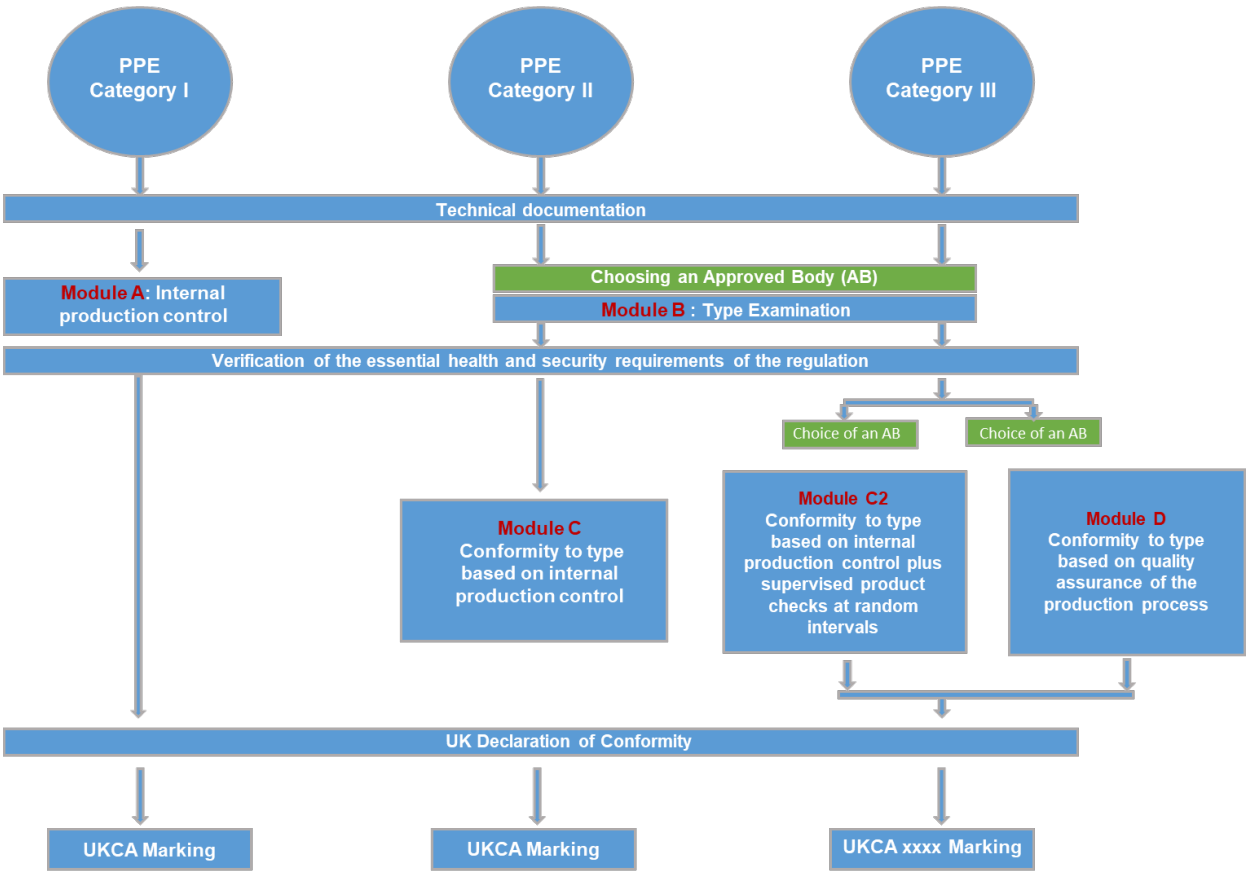
The (Regulation (EU) 2016/425 as brought into UK law and amended) and the Personal Protective Equipment (PPE) (Enforcement) Regulations 2018 as it applies to the GB Market states that the UKCA marking is mandatory for PPE categories II and III. With the UKCA marking, the manufacturer certifies that the product meets the Essential Health and Safety Requirements and that the product is placed on the market in accordance with the legislation. The technical requirements are described in the designated standards.

The purpose of product certification is to assess the compliance of a PPE with the provisions of the (Regulation (EU) 2016/425 as brought into UK law and amended) and the Personal Protective Equipment (Enforcement) Regulations 2018 as it applies to the GB in the development phase or the production phase and to attest this compliance.

2 Subject and scope

This document specifies the operating conditions of the certification of PPE associated with the UKCA marking. The different PPE involved are defined and specified by designated standards.

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



ALIENOR CERTIFICATION Ltd is approved to perform module B and module C2. Module C2 is reserved for PPE **risk** category III. **The scope of operation can be found in this link: https://www.gov.uk/uk-market-conformity-assessment-bodies/alienor-certification-ltd**

3 Definitions

Applicant: Legal entity requesting the conformity certification of a product and who is committed to maintaining this conformity. This legal entity is either the manufacturer or its authorised representative in Great Britain (GB). Even if a third party (ex: consultant) makes the request, the manufacturer remains responsible for the conformity of their product.

Approved body: A conformity assessment body approved by the Secretary of State. to undertake conformity assessment activities (test, Type-Examination, periodic checks) within the framework of the standard in question and for UKCA marking of products to be placed on the GB market

Authorised Representative – A person appointed in writing by a manufacturer to perform specific tasks for the manufacturer. Authorised representatives for the GB market must be based in the UK. Manufacturers remain ultimately responsible for ensuring these tasks are carried out properly.

Declaration of Conformity: document prepared by the manufacturer which must detail, among other things, the following:

- the name and address of the manufacturer and, where applicable, their authorised representative. This must be kept by the manufacturer for a period of ten years from the date on which the product was placed on the GB market and it must be made available to the enforcing authority upon request
- the specific product to which the declaration is referring

Designated standards: A standard developed by consensus, which is recognised by government in part or in full by publishing its reference on GOV.UK in a formal notice of publication. For the GB market, and depending on the product, a designated standard can be a standard adopted by any of the recognized standardization bodies. By following designated standards, manufacturers can claim, 'presumption of conformity' (which can be countered by evidence) with the Essential Health and Safety Requirements.

Evaluation report: report made by an approved body summarising the Type-Examination activities performed and the results.

Manufacturer – A person who manufactures PPE or has PPE designed or manufactured and markets that PPE under their name or trademark.

Module C2: Conformity to type based on internal production control plus supervised product checks at random intervals: periodic control made by an approved body in order to check if the PPE still complies with the Essential Health and Safety Requirements, by controlling the

homogeneity of the production and its compliance with the technical file submitted during the Type-Examination.

PPE: Personal Protective Equipment

Type-Examination (Module B): part of the conformity assessment procedure by which an approved body examines the technical design of a PPE, verifies and attests that the technical design of the PPE complies with the requirements of the regulation. Applicable to products of risk category II and III.

Type-Examination Certificate: a statement made by the approved body attesting that the PPE complies with the Essential Health and Safety Requirements.

UKCA marking: (UK Conformity Assessed) marking used for certain goods (including PPE) being placed on the GB market, in place of the CE marking which is the conformity marking used in the European Union, by which the manufacturer indicates that the PPE conforms with the applicable requirements set out in the (Regulation (EU) 2016/425 as brought into UK law and amended) and the Personal Protective Equipment (Enforcement) Regulations 2018 as it applies to the GB Market providing for its affixing.

4 Certification procedures

4.1 Application for certification

If a company wishes to have a PPE certified, they get in contact with ALIENOR CERTIFICATION Ltd. This initial phase mainly consists in exchanging general information about the certification process, including:

- ✓ The definition of the product (or of the panel of products), based on the production process and the characteristics of the product, through the SUP/EVAL-002 UKCA marking application form.
- ✓ A feasibility study with criteria such as prior experience and competence. In some cases, the service might be declined if there's a lack of capability for an application.

ALIENOR CERTIFICATION Ltd shall provide the same level of certification service to all applicants without any discrimination.

4.2 Initial control and application review

During this phase, the applicant receives the SUP/EVAL-019 Client Estimate. The applicant accepts the certification agreement through the signature of the price offer and acknowledgement of the SUP/QUA-050 General Terms and Conditions of sale for Certifications and this SUP-QUA/026 certification program, which explain the rights and duties of both parties and a timeframe for the work to be done.

The required documents that must be made available for ALIENOR CERTIFICATION Ltd are: SUP/EVAL-001 Technical file checklist, SUP/EVAL-025 Certificate of first application

for Module C2, and, if applicable, SUP/EVAL-036 Authorization Letter, SUP/EVAL-018 Sworn Statement-Manufacturer and SUP/EVAL-035 Sworn Statement-Instructions and Marking (in application of Article 12 of the Regulation 2016/425 as brought into UK law and amended)

The ALIENOR CERTIFICATION Ltd personnel involved in the evaluation phase checks whether the information in the technical file provided by the company is complete. If necessary, test samples or additional information to complete the file will be requested.

The applicant provides the necessary documents with identification and description of the products and materials defined. The deadline for the service, listed in the estimate, starts only after receipt of all these documents. The sole purpose of this first check is to verify the integrity of the file and in no way implies that the technical file or the PPE complies with the legal requirements.

4.3 Evaluation

4.3.1 Type-Examination: Module B

A Type-Examination is carried out. The technical file is the essential input for the verification of the Essential Health and Safety Requirements of the Regulation (Annex II and III). The technical details are defined in designated standards or other technical specifications.

The tests are carried out in a subcontracted laboratory designated by ALIENOR CERTIFICATION Ltd according to the applicable subcontracting rules. These rules are based in particular on the accreditation to the ISO/IEC 17025 standard or qualification to the applicable requirements of ISO/IEC 17025 or ISO/IEC 17020. ALIENOR CERTIFICATION Ltd assumes full responsibility for the tasks performed by its subcontractors. In cases where the client already has test reports, these may be used as long as they are issued by ISO/IEC 17025 accredited testing laboratories and that they are less than 5 years old. Where reports are older than 5 years old, then ALIENOR CERTIFICATION Ltd reserves the right to request additional supporting documentation, such as more recent ~~check~~ test data. In all cases, ALIENOR CERTIFICATION Ltd is the sole decision-maker as to whether or not to accept the test reports.

By default, the manufacturer’s instructions and information will be validated in English. In the absence of the instructions in English, the client is responsible for the translation.

With the conclusions of the test, ALIENOR CERTIFICATION Ltd issues an SUP/EVAL-012 Evaluation report.

In case of non-compliance or missing information concerning the Type-Examination, the business manager asks the applicant to take appropriate corrective actions and/or provide the necessary elements for the performance of the Type Examination. Without any return from the customer within 3 months, the file will be closed.

4.3.2 Periodic checks for risk category III PPE: Module C2

As soon as the certificate is issued and during its period of validity, ALIENOR CERTIFICATION Ltd plans surveillance which includes the performance of periodic checks to verify the homogeneity of the production and the conformity of the PPE to the type described in the type-examination

The manufacturer can choose between modules C2 or D, but they shall communicate their choice in the technical file with the Type-Examination. Each year, following the initial certification, ALIENOR CERTIFICATION Ltd contacts the certificate holder to carry out surveillance ~~visit~~ to verify the conformity to the type of the PPE and the homogeneity of the production.

If a customer wishes to delegate Module C2 to ALIENOR CERTIFICATION Ltd, whereas the initial type-examination was done by a different Approved Body, ALIENOR CERTIFICATION Ltd will request documents such as SUP/EVAL-028 Application for Module C2 evaluation, Technical File and supporting documents, and will get in contact with this Approved Body in case there is any difficulty linked to the evaluation of the conformity of the sample.

ALIENOR CERTIFICATION Ltd carries out the Module C2 control along 2 axes:

• **Conformity to the type of the PPE:** ALIENOR CERTIFICATION Ltd chooses an appropriate sample of the PPE manufactured in a location agreed on with the manufacturer. The sampling methods as well as the tests performed will be subject to a contract review with the manufacturer.

ALIENOR CERTIFICATION Ltd will subcontract the critical tests, according to the same methods as those defined in § 4.3 of this document. However, the verification of the manufacturer's instructions and markings will be carried out at each control.

• **Homogeneity of production**: ALIENOR CERTIFICATION Ltd shall carry out an audit of the production site as a risk assessment approach aiming to evaluate the effectiveness of the **production** control processes run by the manufacturer and to determine the sample size. This audit will be followed by simple product checks to verify the homogeneity of production.

After the check is made, ALIENOR CERTIFICATION Ltd issues a module C2 evaluation report summarising the conclusions, it determines if the PPE is still compliant with the standard requirements and if it corresponds to the sample sent for the Type-Examination.

In case of absence of sample (lack of stock), and in case ALIENOR CERTIFICATION Ltd has completed Module B for the Type-Examination Certificate, the latter will be suspended until the sampling is possible and the module C2 decision is issued. ALIENOR CERTIFICATION Ltd will inform the competent authority of the situation. From the day of receipt of notification, this communication represents a prohibition for the client to put the product on the market until the situation is solved.

4.4 Evaluation Review

In case of non-compliance in the Module B or Module C2 evaluation report results, the certification manager asks the business manager to contact the applicant to correct the mistake before issuing a SUP/EVAL-016 Review and decision sheet

4.5 Certification decision

Depending on the results of the evaluation report issued and signed by the business manager, ALIENOR CERTIFICATION Ltd makes one of the following decisions:

- ✓ Positive, if all is compliant concerning Module B or Module C2, then the certification manager signs the review and decision sheet, and SUP/EVAL-010 Type-Examination Certificate is issued. With a positive decision the SUP/EVAL-024 Module C2 decision is issued and valid for 1 year.

- ✓ A negative decision concerning the Type-Examination if it is impossible to prove the conformity of the PPE, then ALIENOR CERTIFICATION Ltd will formulate a proposition of SUP/EVAL-013 Refusal of Type-Examination Certificate and notify the client.

- ✓ In case of a negative decision concerning the Module C2 control or if the client fails to provide an action plan to ALIENOR CERTIFICATION Ltd within 15 days after receipt of the non-conformities, ALIENOR CERTIFICATION Ltd may suspend or, if necessary, withdraw the Type-Examination Certificate and notify the authorities.

  The Type-Examination Certificate contains:
  - The date of issue (date of signature)
  - The date of the beginning of validity (date of the decision)
  - The date of renewal (when applicable)
  - The expiry date

4.6 Renewal of the Type-Examination Certificate

The renewal of the Type-Examination Certificate is fixed 5 years after the beginning of the validity date of the certificate. The manufacturer must apply 6 to12 months before the expiry date of the certificate. It can be done according to 2 cases:

- ✓ A simplified procedure: When there is no modification of the type or no change in the State of the art. In this case, ALIENOR CERTIFICATION Ltd will carry out a review and decision without issuing an evaluation report and will send the client the renewal of the Type-Examination Certificate.

- ✓ Evolution of the state of the art and/or modification of the type: in this case, the renewal cannot be a simplified procedure because it implies a modification of the technical file

or additional tests. ALIENOR CERTIFICATION Ltd will carry out a re-certification, identical to a module B certification, with technical tests as required to validate the modification(s) and will send to the client the test report, the evaluation report, and the renewal of the Type-Examination Certificate.

ALIENOR CERTIFICATION Ltd ensures that the renewal procedure is finalized before the expiry date of the Type-Examination Certificate, following Annex V point 7.5 of the (Regulation (EU) 2016/425 as brought into UK law and amended) and the Personal Protective Equipment (Enforcement) Regulations 2018 as it applies to the GB Market

4.7 Changes affecting certification

ALIENOR CERTIFICATION Ltd will inform the customer of all changes that may have an impact on the certification of their product, such as any technical evolution of designated standards or requirements of this document and the time for transition or implementation.

5 Manufacturer's obligations

Each applicant is presumed to comply with the SUP/QUA-050 General Terms and Conditions of Sale for Certification and this document, which acts as a contract between ALIENOR CERTIFICATION Ltd and the manufacturer, and is signed in the Client Estimate or agreed upon the provisions of an ongoing agreement.

In addition, the applicant is presumed to comply with the requirements of the (Regulation (EU) 2016/425 as brought into UK law and amended) and the Personal Protective Equipment (Enforcement) Regulations 2018 as it applies to the GB Market

The manufacturer undertakes to:

- ✓ Ensure that the PPE, before placing it in the GB market, has been designed and manufactured in accordance with the applicable Essential Health and Safety Requirements. These are set out in Annex II of the Regulations 2016/425.
- ✓ Have a relevant conformity assessment procedure carried out and technical documentation drawn up.
- ✓ Draw up a declaration of conformity, ensure that it accompanies the product (or information as to where it can be accessed) and keep it with the technical documentation for 10 years after the PPE has been placed on the GB market.
- ✓ Affix the UKCA marking visibly, legibly, and indelibly to the PPE. Where it is not possible or warranted, on account of the nature of the PPE, it must be affixed to the packaging and the accompanying documents[1].
- ✓ Keep at the disposal of ALIENOR CERTIFICATION Ltd or its representative: all the information and documents necessary, on paper or electronically, to demonstrate the compliance of the PPE with the Regulation

[1] In any event, until 31 December 2025, see footnote 4 here, the UKCA marking may be affixed to a label affixed to, or a document accompanying, the PPE.

- ✓ Ensure that procedures are in place for series production, to remain in conformity.
- ✓ Changes in the design or characteristics of the PPE and changes in the designated standards or in other technical specifications by reference to which the conformity of the PPE is declared shall be adequately taken into account. These modifications shall require additional approval in the form of an addition (through a SUP/EVAL-020 Application for an additional certificate) or a new Type Examination Certificate.
- ✓ When deemed appropriate, with regard to the risks presented by PPE, the manufacturer shall, to protect the health and safety of consumers and other end-users, carry out sample testing of PPE made available on the GB market, investigate, and, if necessary, keep a register of complaints of non-conforming PPE and PPE recalls, and shall keep distributors informed of any such monitoring.
- ✓ Ensure that all PPE placed on the GB market bears a type and serial or batch number, or other element allowing its identification. The manufacturer should also include its name, registered trade name or registered trademark, and postal address on the product. Where the size or nature of the PPE does not allow this then it may be provided on the packaging or accompanying documentation.
- ✓ Ensure that PPE is accompanied by instructions and safety information as set out in point 1.4 of Annex II to the Regulation, which is clear, legible, and in easily understandable English
- ✓ Manufacturers who consider or have reason to believe that PPE which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that PPE into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the PPE presents a risk, manufacturers shall immediately inform the enforcement authority to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken. **Read more information on how to notify the MSA[2].**
- ✓ To notify ALIENOR CERTIFICATION Ltd of any change made to the production control system as described in the file submitted to ALIENOR CERTIFICATION Ltd and likely to call into question the validity, content, or scope of the certificate

Examples of changes may include the following:

- A change of company name,
- A change of laboratory,
- A change in the production process,
- The addition or deletion of production sites
- Major modification of the quality management system

6 Penalties for a violation

The penalties applied to a manufacturer who does not respect their obligations (5 above) might be the suspension, withdrawal, or termination of the certificate. These penalties,

[2] https://www.gov.uk/government/publications/business-notifications-of-unsafe-and-noncompliant-products

taken by the authorized person in ALIENOR CERTIFICATION Ltd, are preceded by a warning and a formal notice to take corrective measures in 15 days .

In case of an unexplained refusal to pay the invoice, no certificate will be issued to the client.

ALIENOR CERTIFICATION Ltd assesses the seriousness of the offence and sanctions accordingly.

If certification is terminated, withdrawn, or suspended, ALIENOR CERTIFICATION Ltd shall make all necessary modifications to formal product certification documents, public information, authorizations for use of marks, etc., to ensure it does not indicate that the product continues to be certified.

If a scope of certification is reduced, ALIENOR CERTIFICATION Ltd shall make all necessary modifications to formal product certification documents, public information, authorizations for use of marks, etc., to ensure the reduced scope of certification is communicated to the client and specified in product certification documentation and public information.

6.1 Suspension

A process consisting in temporarily invalidating a Type-Examination Certificate for all its scope. A client's UKCA Module B Type Examination Certificate may be suspended for the following reasons:

- Failure to comply with the contractual requirements relating to certification,
- Non-compliance with the provisions laid down in the surveillance procedure,
- Deviations from the specific requirements covered by the certification
- Non-compliance with regulatory requirements by certification,
- Following the outcome of a complaint treatment

ALIENOR CERTIFICATION Ltd shall inform the client in writing with acknowledgement of receipt that their certificate has been suspended, the reason(s) for the suspension, and the actions required to reinstate the certificate. Such suspension shall take effect on the date of written notification.

The certificate shall be reinstated after suspension if the client provides evidence of remedial actions of non-conformities in the 6 months following the suspension. If not, ALIENOR CERTIFICATION Ltd shall withdraw the certificate.

To reinstate the certificate, the client has the option of performing additional tests. These will be sent to ALIENOR CERTIFICATION Ltd for evaluation.

6.2 Withdrawal or termination

A certificate shall be withdrawn or terminated (at the request of the client) following:

- Permanent termination of activity,
- Repeated non-compliance with contractually defined certification requirements,
- Repeated non-compliance from the specific or regulatory requirements covered by the certification /Non-acceptance of contractually defined monitoring phases
- Failure to comply with the provisions laid down in the surveillance procedure after the surveillance period has elapsed
- Fraudulent use of the certificate, or fraudulent practice of its activity,
- No activity with the certificate issued for more than one year
- Following the outcome of a complaint
- On proof of double certification, the certificate shall be withdrawn for the relevant certification within one month of identification of the double certification. In addition, ALIENOR CERTIFICATION Ltd informs the second Approved Body of the identified dual certification
- Failure to implement any remedial actions of non-conformities by the client in the 6 months following the suspension of the certificate

ALIENOR CERTIFICATION Ltd shall inform the client in writing with acknowledgement of receipt that their certificate has been withdrawn or terminated, the reason(s) for the withdrawal or termination, and any actions required. Such withdrawal or termination shall take effect on the date of written notification to the client.

A withdrawal of the certificate cannot be reinstated, the client will have to make a new application for the product.

7 Appeal procedure

The applicant has the right to appeal against a certification decision of ALIENOR CERTIFICATION Ltd. This must be done in writing and must be addressed to ALIENOR CERTIFICATION Ltd. Upon receipt, ALIENOR CERTIFICATION Ltd acknowledges receipt of the appeal by e-mail. The "PRO 007 Complaints and Appeals" procedure is available on the ALIENOR CERTIFICATION Ltd website.

The appellant shall have 15 days from notification of its refusal, reduction, withdrawal, or suspension, to appeal.

To be admissible, the appeal must be motivated and relate to the decision taken by ALIENOR CERTIFICATION Ltd. The client is then informed of the admissibility or not of the appeal and the time required to process the file.

Admissibility is in no way linked to the legitimacy of the motivation.

- ✓ If the appeal is declared inadmissible, the president of ALIENOR CERTIFICATION Ltd shall inform the parties concerned in writing of the reasons for this declaration of inadmissibility.

- ✓ If the appeal is declared admissible, the president of ALIENOR CERTIFICATION Ltd shall convene an appeal committee. The appellant has the opportunity to explain and defend the case at the appeal committee meeting.

The appeal committee reviews the file and decides to maintain or not the certification decision. This is communicated in writing, requesting acknowledgement of receipt, from all parties involved. The decision of the appeal committee is final and binding for the two parties.

Regardless of the decision of the extraordinary appeal committee, the manufacturer cannot claim damages from ALIENOR CERTIFICATION Ltd for any damages incurred.

8 Confidentiality

ALIENOR CERTIFICATION Ltd shall deal with all the information concerning the applicant with the utmost confidentiality and shall not share them with a third party without the written agreement of the applicant. This is not the case for information that must be shared with the competent authorities or other approved bodies such as withdrawal, refusal, or suspension of certificate. The client shall be notified of the information provided unless prohibited by law.

9 Impartiality

ALIENOR CERTIFICATION Ltd has taken all necessary measures to guarantee the impartiality of decisions concerning certification. This is supervised by the impartiality safeguarding mechanism who meets at regular intervals. Manufacturers, as well as consumers, authorities, and experts, are represented by the members of this impartiality safeguarding mechanism committee whose terms are described in ALIENOR CERTIFICATION Ltd.'s Quality Manual.

10 Abusive use

Alienor Certification Ltd has ownership of the certificate and mark of conformity. As such, the use of UKCA marking with the reference to ALIENOR CERTIFICATION Ltd and its Approved Body number for a PPE without any delivery of a Type-Examination Certificate from ALIENOR CERTIFICATION Ltd is considered abusive and misleading use, such as incorrect references and shall be penalised.