REGULATIONS FOR PRODUCT CERTIFICATION (REGULATION FOR PRODUCT CERTIFICATION)

ROLES ROLES	Business Function (Business function)	Signature Date – DD/MM/YYYY (Signature date - DD/MM/YYYY)
Author (Author)	Technical Director	28-06-23
Reviser (Reviewer)	Sales Manager	28-06-23
Approver (Approver)	Sole Director	28-06-23

The approval flow refers to the approval of the following documents, which form an integral part of these Regulations. The same are prepared by the Body (CME) and sent to the Applicant at the same time as sending the form for the Application for Certification.

	Approved Documents	Reference
◆	GDPR	THIS REGULATION
◆	GDPR **-HYDB**	REVISION HISTORY AND MAILING LIST

INDEX

1 PURPOSE AND SCOPE

1.1 Generality

These Regulations, approved by the Top Management of Ente Certificazione Macchine srl (hereinafter ECM) and by the Committee for the Safeguarding of Impartiality (hereinafter CSI), establish the procedure that is applied by ECM for the certification of products and production processes, with the relative concession of the use of conformity marks. ECM establishes the conditions for the application of its trademark as indicated in chapter "4 - Concession of Use of Trademarks and Distinctive Signs" of use for the various homogeneous sectors of products admitted to certification. For products that can be certified in these sectors, the provisions of paragraph "2.1 - Certifiable Products, Applicable Procedures and Standards".

The information in this Regulation on certifiable products can be downloaded from the websites listed below, by searching for the company name "ENTE CERTIFICAZIONE MACCHINE SRL" (hereinafter ECM).

	WEBSITE	SEARCH
	Home ECM (www.entecerma.it)	ENTE CERTIFICAZIONE MACCHINE SRL Customer Service > Official Documents > Regulations
	ACCREDIA (www.accredia.it)	Databases > Accreditations > Accredited and Recognized Bodies
	European Commission (https://ec.europa.eu/growth/tools-databases/nando/)	Notify Body Nando System > Notified Body number: 1282

1.1.1 Revision history

The revision history describes "Revision List, Approval Date, Reasons for Revision".
The revised document can be sent to interested parties.
The document that indicates the revision history and the list of people to whom it was sent is (GDPR -HYDB)".
These regulations are available to interested parties on the CME website (see "1.1 Generality"),

1.1.2 Applicability

These Regulations apply to the activities carried out by ECM, in relation to the CE Product Certification and the related Quality Systems for the products to be certified.

1.1.3 Formation

On the occasion of each revision and issuance of these Regulations, Training/Information will be provided to all the CME staff involved.

1.1.4 ECM's Rights and Obligations

1.1.4.1 ECM Rights

- ECM reserves the right to use employees and/or freelancers to carry out conformity assessment activities.
- Reject an application for certification if there is a risk of impartiality due to previous consultancy activities carried out for the same organisation regarding the purpose of the certification;
- In addition, CME reserves the right to refuse a certification application if it conflicts with the requirements or conditions of the organization of CME activities;
- For modules that provide for Quality Certification, manage the procedures provided for by the "Decision 768/2008/EC" and the relevant Directives where surveillance is required for the period of validity of the certificate.

1.1.4.2 Duties of CME

- Apply the requirements set out in this Regulation to aspects specifically related to the scope of the certification itself;
- Keep all internal management system documentation up-to-date
- Prepare, provide and maintain a detailed description of the certification activity, including the application for certification, the assessment activities, as well as the process for issuing, maintaining, reducing, extending, suspending, revoking the certification and renewal process, including in the case of a risk of impartiality;

- If you are formally informed of this, notify the competent bodies and the accreditation body (see applicable directives/regulations) of the cases in which certified companies are involved in processes related to product/service liability and safety laws;
- the NB, as per Directives and or Regulations, has the duty to activate the appropriate insurance coverage required by law;
- Inform the Market Surveillance Authority and, if applicable, ACCREDIA (where relevant) of facts and situations that may compromise consumer safety as a result of the use of a certified product;
- Communicate to the Applicant the composition of the audit team, including the members of the Regulatory Authority and/or ACCREDIA; In any case, ECM reserves the right to subsequently replace one or more team members in the event of need or conflicts that have arisen after the agreements have been made;
- Guarantee the authenticity of attestations. On the ECM website there is a "**Customer Service >Certificate Search**" section that allows you to verify the authenticity of the certificates;
- In the event that ECM receives a certificate that turns out to be false, ECM itself publishes the data of such documents on the ECM website in the section "**Customer Service > False Documents and Improper Use of No. 1282**", as well as deciding whether to report them to the Judicial Authority;
- Management of any complaints and appeals received in an official manner and adequately dealt with as indicated in the following paragraphs;
- Management of regulatory and/or legislative updates with all active customers;

1.1.5 Rights of the organization requesting certification (customer)

The Organization to which the certification is issued may:

- Where applicable, it can affix the identification number of the Notified Body Ente Certificazione Macchine S.r.l. (n° 1282) next to the CE Mark required by the Directive in the manner provided for by the same;
- It may publicise the certification in the manner it deems most appropriate, provided that it complies with the rules defined in the chapter "4 - Concession of Use of Trademarks and Distinctive Signs";
- You can express an opinion on the degree of satisfaction with the service received both through direct communication and through the customer satisfaction form on the ECM website, so that ECM can use this information to activate ways to improve the service provided;
- It may formulate and communicate in writing any complaints and appeals, with respect to the content of the findings found during the conformity assessment activities, giving written notice to ECM;
- You can request the Certificate from ECM on any type of support, provided that you bear the related costs.
- You have the right to request the replacement of the verification team, within 5 working days, if there are justified conflicts of interest.

1.2 Purpose of certification

The purpose of the certification of a product is to give assurance to the customer and to the market, with an adequate level of confidence, that the product is considered compliant and is kept in compliance with the certification requirements of the applicable European Directives and or Regulations, the standards and technical specifications of reference. This purpose is achieved through documentary evaluation, testing and verification, conducted before the certification is issued and subsequently, through periodic surveillance checks where it is required.

The certification of a product is defined by the European Directives, and or European Regulations and the criteria established by them, constitute a fundamental reference to which ECM strictly adheres. In accordance with the provisions of the "**Decision 768/2008 published in the Official Journal of the European Union on 13.8.2008**" by Annex II, Conformity Verification Procedures. This requirement is referred to in the forms linked to these Regulations, which the Client comes into possession of once a request for certification at CME has been activated, such as the forms "Data Collection (QA07-17065_M01)", **"Application for Certification (QA07-17065_M04)" and** "Quote, Offer, Contract (QA07-17065_M05)**"** in the latest current revision, and the specific forms to be used by Clients to submit an official application for CE certification of a product with regard to ECM.

Our purpose, described in this document, is to define the relationship between ECM, as an independent third party, and its client organizations with regard to Product Certification for the EU directives and regulations for which ECM has obtained Accreditation and Authorization. Establish the rights and duties of CME and the Applicant with regard to certification procedures, the management of non-conformities, the management of complaints and appeals, the regulatory requirements applied with objectivity and absence of discrimination.

ECM does not and cannot assume any responsibility for the positive outcome of this assessment activity and, consequently, to issue the relevant certification.

1.3 Committees

1.3.1 CoC Certification Committee

The activity of the Certification Committee (CoC) is explained in the "CoC Committee Internal Regulations" of ECM. Each Member of the CoC Committee must be free from any commercial, economic, financial and other pressures that could influence his or her decisions.

The tasks assigned to the Certification Committee are mainly:

- Review of the evaluation activities of the certification process
- Decision for the issuance of certification to the "Manufacturer/Authorised Representative"

1.3.2 CSI Impartiality Safeguarding Committee

The activity of the Committee for the Safeguarding of Impartiality (CSI) is explained in the "Internal Regulations of the CSI Committee and Internal Procedures" of ECM. The members of the CIS Committee must be free from any commercial, economic, financial and other pressures that could influence their decisions.

The CSI provides an opinion on:

- Policies and principles relating to the impartiality of certification activities;
- Any tendency on the part of ECM to allow commercial or other considerations to prevent the consistent and impartial provision of certification activities;
- Aspects that influence impartiality and trust in certification, including transparency;

2 GENERAL TERMS AND CONDITIONS

2.1 Certifiable Products, Applicable Procedures and Standards

2.1.1 Request Analysis (Data Collection for Bid Preparation)

Before proceeding with the formulation of the CME certification offer, through the management body, it analyzes the request of the potential "Manufacturer/Authorized Representative" to check the relevance and feasibility of the certification process of the product to be certified to the categories of qualification in possession.

2.1.2 Certifiable products

Within the identified sectors and on the basis of the standards or technical specifications to be applied for the relative conformity assessment, the products for which certification will be requested are established by the "Manufacturer/Authorised Representative" under its own responsibility with reference to the sector concerned, taking into account the following constraints:

- Certification can be issued for prototypes, one-offs and/or mass-produced products;
- The use of technical specifications in place of harmonised standards should be restricted to cases where an appropriate national or international standard is not available, but these technical specifications must have been approved on the basis of a broad consensus.
- The body has the right to be aware of the serial numbers and numbers of batches not yet marketed or in the process of being marketed by the customer who have a certification revoked (see "3.4 Certification process – Product verification").

ECM has the burden of assessing the adequacy of these elements.

2.1.3 Guidelines for certification

For the certification of a product, it must be subjected to the tests and verifications indicated, such as type tests, the requirements of which are contained in the standards or technical specifications in force at the time of application.

2.1.4 PRD Certification Process Workflow

The Annex "Product Certification Workflow (GDPR -WF)" illustrates the general process of the certification process with regard to the various procedures applicable for each of the sectors included in the Scope of ECM Authorizations (see "3.1 - REGULATORY AND LEGISLATIVE REFERENCES").

2.2 Requirements for the Manufacturer/Authorised Representative applying for certification

2.2.1 Certificate Applicant

The certification referred to in these Regulations may be requested by the "Manufacturer/Authorised Representative" of the relevant products or by an Organisation (Authorised Representative), which has a specific written agreement with the same authorising it to act on its behalf in relation to certain activities.

2.2.2 Granting of certification

The certification will be granted to the "Manufacturer/Authorised Representative" after verifying the conformity of the product with the relevant requirements of the Directives and/or Regulations, standards or technical specifications, and any reports from other NBs.

2.3 Delivery and collection of products

(p.01) The products to be tested must be sent to ECM by the "Manufacturer/Authorised Representative" requesting certification, accompanied by the documents required by current legislation.

€ If, in exceptional cases, or when provided for by Directives, Regulations or Reference Standards, ECM is required to take care of the samples taken, transport or import of the products, the related expenses incurred by ECM will be invoiced with the increase provided for in the Tariff in force.

(p.02) The products selected by the CME representatives for control and surveillance purposes (see "6.2.4 - CME Officers") they must be sent, by the "Manufacturer/Authorised Representative" requesting the certification, to the ECM headquarters; The "Manufacturer/Authorised Representative" must take all precautions to ensure that the products arrive at their destination in good condition.

(p.03) The samples subjected to the tests must be collected by the "Manufacturer/Authorised Representative" concerned no later than 30 days after the notification of the result of the tests. If these samples are not collected within the indicated deadline, ECM will send the "Manufacturer/Authorised Representative" a communication by certified e-mail informing him/her in advance of the return or disposal of the aforementioned products at public landfills, together with details of the estimated costs for the two options, which the "Manufacturer/Authorised Representative" will bear directly.

The prototypes and tested samples, if returned, are shipped in the condition they are in after the tests. The "Manufacturer/Authorised Representative" is aware and accepts that the product may be damaged as a result of the execution of destructive tests required by the applicable standards and or technical specifications.

2.4 Publicity of the certification application

The "Manufacturer/Authorised Representative" may not publicise the application for certification until it has obtained the relevant approval from ECM.

2.5 Obtaining and Maintaining Certification – Amounts Due

The issuance of the certification and its maintenance are subject to:

- the signing for acceptance of the contract and all the clauses provided for and including the acceptance of these regulations;
- the positive outcome of the assessments of compliance with the requirements of the applicable directives and/or laws/regulations;
- the payment of the amount for the management of the activities related to the issuance of the certification;
- the payment of the amount for the planned verification activities;
- the payment of the amount for the maintenance of the concessions, if any, (so-called "fees");

2.6 Resources used by ECM for conformity assessment

(p.01) The testing and verification activities on products for certification, as well as control tests, are carried out by ECM at its own laboratories or those of the manufacturer and/or its authorized representatives (as Witness).

(p.02) The verification activities at the premises of the manufacturer and any authorised representatives are carried out by ECM employees or external personnel, qualified according to specific procedures, in compliance with the applicable regulations, and required to comply with the obligations of secrecy and impartiality.

On the occasion of the verification c/o the manufacturer, in relation to activities that involve the verification of the Quality System, it is necessary that the Technical Expert (ET) and the System Auditor, who can be the same person if in possession of the necessary requirements, appointed by ECM are present. Following the first verification, on the occasion of the annual

surveillance activity, the technical expert and the system auditor appointed by ECM will be present again for the documentary analysis and the verification of the maintenance of the compliance requirements of the certified product.

For the sampling activity only, the auditor appointed by ECM is not present.

The Client has the full right to reject the auditor and/or the operating technician proposed by ECM, giving a reasoned written justification at least 5 working days in advance, with respect to the date set for the visit.

2.7 Subcontracting

ECM reserves the right to subcontract part of the requested Service to third parties. ECM guarantees impartiality and confidentiality of the subjects involved, whether they are a laboratory or technical/auditor staff.

2.8 The Customer/Supplier will be informed of the subcontracted activities, he can object within 5 working days from the date of communication. For the management of suppliers and subcontractors and laboratories, reference is made to the specific procedure. Prohibition of generating conflicts of interest and carrying out consultancy activities

In carrying out the activities provided for in these Regulations, ECM does not provide in any way consulting services related to the area for which certification is requested, or certification has already been obtained. In addition to not carrying out consultancy activities, ECM does not intervene in the design, manufacture, marketing, use or maintenance of products, nor does it represent subjects engaged in activities related to the area for which certification is requested or already obtained.

2.9 Terms and Definitions

In this document, the terms and definitions set out in the Directives, Regulations, and reference standards apply. The following terms and definitions are as follows:

- '**manufacturer**' means any natural or legal person who manufactures, has PPE machinery, apparatus or equipment designed or manufactured, and markets it under his own name or trade mark.
- '**authorised representative**' means any natural or legal person established in the Union who has received a written mandate from a manufacturer authorising him or her to act on his behalf in relation to certain activities.
- "**Concessionaire**" is the "Manufacturer/Authorised Representative" who receive from ECM the use of the Certificate following a positive resolution by the ECM Certification Committee.
- '**authorised representative**' means a natural or legal person established in the Union who has received a written mandate from a manufacturer authorising him or her to act on his behalf in relation to certain tasks;
- **'importer**' means a natural or legal person established in the Union who places on the Union market an apparatus originating in a third country;
- '**distributor**' means a natural or legal person in the supply chain, other than the manufacturer and importer, who makes an appliance available on the market;
- '**economic operators**' means the manufacturer, the authorised representative, the importer and the distributor; Dir 2014/30/EU.
- 'process' means all activities for the manufacture of machinery, equipment, PPE or a component thereof.
- '**audit team**' means a person, or group of persons, who carries out on-premises audits and sampling (where applicable) for the purpose of maintaining EU certification. The number, skills and role of the members of the audit team are decided by ECM, in order to ensure an analytical capacity suitable for the object of the assessment.
- '**assessment activity**' means an activity carried out by ECM to assess the conformity of the product with respect to the applicable reference requirements; it can be documentary, inspection (in the factory) or test.
- '**homogeneous batch of product**' means a homogeneous quantity from which statistically significant samples can be taken for the appropriate examinations in order to assess their characteristics and compliance with the specified requirements.
- "**technical file**" means all the documentation required by the various Annexes of the Directives and by the mandatory Regulations that characterize the equipment to be certified.
- **'marketing**' means the first making available of a product on the Union market;
- 'market surveillance authority**' means the authority of a Member State responsible for market surveillance in the territory of that State;**
- '**making available on** the market' means the supply of equipment for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- '**placing on the market**' means the first making available on the Union market of an apparatus; Dir 2014/30/EU.

- '**technical specification**' means a document that prescribes the technical requirements to be met by the equipment; Dir 2014/30/EU.
- '**harmonised standard**' means the harmonised standard referred to in point (c) of Article 2(1) of Regulation (EU) No 1025/2012; Dir 2014/30/EU.
- '**accreditation**' means accreditation as defined in point (10) of Article 2 of Regulation (EC) No 765/2008; Dir 2014/30/EU.
- '**national accreditation body**' referred to in point (11) of Article 2 of Regulation (EC) No 765/2008; Dir 2014/30/EU.
- '**conformity assessment**' means the process of demonstrating compliance with the essential requirements of this Directive relating to an apparatus;
- 'conformity assessment body**' means a body that carries out conformity assessment activities, including calibrations, tests, certifications and inspections;**
- **'recall**' means any measure aimed at obtaining the return of equipment which has already been made available to the end-user;
- 'withdrawal' means any measure to prevent the making available on the market of an appliance in the supply chain; Dir 2014/30/EU.
- '**Union harmonisation legislation' means Union legislation harmonising the conditions for the marketing of products;**
- '**CE marking'** means a marking by which the manufacturer indicates that the appliance complies with the applicable requirements laid down in Union harmonisation legislation providing for its affixing to the CE marking.
- '**non-conformity' 'non-conformity**' failure to meet a requirement established by the applicable, essential and safety regulatory references. The condition of non-fulfilment of a requirement may be due to:

i. failure or insufficient consideration of the requirement itself and/or failure or insufficient definition of the criteria and methods adopted for the fulfilment;
ii. lack or insufficient practical implementation of the above criteria and modalities, initially (implementation of the requirement) and over time (maintenance of the requirement);
iii. both of the above lawsuits.

- '**observation**' means an isolated anomaly in controls or procedures that does not pose a potential and significant risk to the conformity of the certified product and/or the effectiveness of the management system.

  or

  A single and isolated anomaly or a set of minor anomalies that does not affect the effectiveness of the system and the manufacturer's ability to ensure the conformity of the product with the conformity requirements for obtaining and/or maintaining certification.
- '**comment (or recommendation)**' means an anomaly in a condition which, in the opinion of the assessor, requires clarification, investigation or improvement in compliance with the overall effectiveness of the management system.

  or

  A finding that does not significantly affect the organizational aspects at the moment but which, in the opinion of the evaluator, represents a potential inadequacy of the system or product.
- '**AC corrective action**' means an activity carried out or carried out by the client, approved by ECM, to resolve NCs and Remarks;
- '**attestation of conformity**' is the formal expression of the results of a conformity assessment which has demonstrated that the specified requirements for a product, process, system or body are met.
- "**complaint**" means a manifestation of dissatisfaction, both verbal and written, by entitled parties (direct customers, indirect customers, Public Authorities, Accreditation Bodies), regarding the services provided by the Body and, in general, its work.
- "**appeal**" means a formal appeal, by specific Parties with cause, against decisions taken or evaluations expressed or certifications issued by the Body.
- "**litigation**" brought before legal proceedings by the successors in title as above to protect their own rights and interests deemed to have been harmed by the work of the Body.

3 CERTIFICATION PROCESS

3.1 REGULATORY AND LEGISLATIVE REFERENCES

The reference standards and directives for CME certification activities within the scope of the application of these Regulations are as follows:

	CODE	DESCRIPTION
◆	UNI CEI EN ISO/IEC 17000	Conformity Assessment - Vocabulary and General Principles

◆	UNI CEI EN ISO/IEC 17020	Conformity assessment - Requirements for the operation of various types of inspection bodies
◆	UNI CEI EN ISO/IEC 17021-1	Conformity assessment - Requirements for bodies providing audits and certification of management systems - Part 1: Requirements
◆	UNI CEI EN ISO/IEC 17025	General Requirements for the Competence of Testing and Calibration Laboratories
◆	UNI CEI EN ISO/IEC 17065	Conformity Assessment - Requirements for Bodies Certifying Products, Processes and Services
◆	UNI EN ISO 19011	Guidelines for audits of management systems
◆	Accredia Requirements	General Regulations, Technical Regulations and Provisions of the Accreditation Body in the schemes and sectors covered by accreditation
◆	EA 2/17	EA Document on Accreditation for Notification Purposes
◆	CME Requirements	Documentation of the Management System of Ente Certificazione Macchine S.R.L.
◆	For verifications in the context of Presidential Decree 162/99 and subsequent amendments art. 13 and 14	See the document "Periodic Verification Regulations (RTVPS)" published on the ECM Website, section "CUSTOMER SERVICE > OFFICIAL DOCUMENTS > REGULATIONS" at the address https://www.entecerma.it
◆	Accreditation Schemes (Directives/Regulations) as defined in the annexes of the 118B Accreditation Certificate	Databases > Accreditations > Accredited and Recognized Bodies

3.1.1 Product Certification Workflow (GDPR -WF)

The Annex "Product Certification Workflow (GDPR -WF)" illustrates the general process of the certification process with regard to the various procedures applicable for each of the sectors included in the Scope of ECM Authorizations (see "3.1 - REGULATORY AND LEGISLATIVE REFERENCES").

3.2 Sending a request from the customer

The "Manufacturer/Authorised Representative" sends ECM a written request by e-mail or telephone presenting his/her requirements relating to the certification of a product.

- The request is handled by ECM (Resp. Commercial and/or Technical DIR) is formalized and its feasibility in economic and regulatory terms is verified. The request can be formalized by a descriptive sheet of the product to be certified as required for each directive or regulation. This tab is the "**Data Collection (QA07-17065_M01)**" module.

3.2.1 Feasibility request for the certification of a product (Required Analysis)

The certification of a product is issued with reference to the individual applicable product directives and standards as well as the certification module applied.

Where the mandatory legislation provides for an initial inspection of the manufacturer, if the assessment activity reveals findings, the product certification cannot be issued until the non-conformities are adequately resolved and/or treated.

Where required by the applied directive and the relevant certification scheme, supervision will be carried out on the production process and/or management system.

The customer's request form will be analyzed and if it falls within the ECM acceptability ranges it will be sent to the next stage. In case of non-acceptability, the client will be notified of the justification for ECM's refusal to continue.

Examples of justification:

1) ECM does not intend to continue with the certification activity for internal reasons.

2) CME: from the analysis of the data provided, there is certain evidence of inappropriate behavior.

3) ECM decides not to accept to continue with the certification activity for management reasons.

3.2.2 Submission of the Offer - Contract

ECM sends the "Application for Certification (QA07-17065_M04)" **form to the "Manufacturer/Authorised Representative"** for an initial identification of the customer; The Form, also available on the website WEB www.entecerma.it must be completed in a congruent manner, must be signed by the "Manufacturer/Authorised Representative" and sent back to UC ECM.

- The Technical Manager (RT) verifies the feasibility of the certification request, examines to verify that the body possesses the requirements, skills, suitable personnel, and equipment necessary to cope with a certification process. Following the positive opinion of RT or DIR, a quote is issued by UC that can be sent to the customer together with the "**Application for Certification (QA07-17065_ M04)".**
- ECM sends the economic proposal (Offer – Contract and Regulations) calculated on the basis of the time/costs established and available in the **"Fee List"** in force, including all costs.
- The "Manufacturer/Authorised Representative" signs the economic proposal for acceptance, or can ask ECM to calculate a discount, or modify the estimate by virtue of changes in its needs, followed by a revision of the Offer – Contract.
- The "Manufacturer/Authorised Representative" sends the form for acceptance of the Offer – Contract.
- ECM carries out the review **"Quote, Offer, Contract (QA07-17065_M05)**" signed for acceptance by the customer, and agrees to take on the task for the certification process.

3.3 Establishment of the application

3.3.1 Opening of the Job

The UC in collaboration with UT is responsible for:

- register the application, carrying out a preliminary review of the application and the related attached documentation;
- agree with the "Manufacturer/Authorised Representative" to carry out the inspection visit(s) aimed at ascertaining the possession of the requirements referred to in the applicable Regulation/Directive;
- the submission, by the "Manufacturer/Authorised Representative", of test and/or evaluation reports of accredited Bodies/Laboratories recognized by ECM, by virtue of mutual recognition procedures and agreements, may allow ECM to omit the performance of some activities provided for in the certification process, when this is compatible with the reference requirements of the scheme concerned.
- communicate to the "Manufacturer/Authorised Representative" the choice of the specimens to be tested; these copies must be sent to ECM or verified or taken directly by ECM at the headquarters of the "Manufacturer/Authorised Representative" or other location indicated by it. The procedure may also be carried out at the manufacturer's premises or at a place indicated by him where the product to be tested is installed;
- after this planning of activities, the certification process continues with the "Verification of the products" and then with the "Verification of the Manufacturer/Authorised Representative".

3.4 Certification process – Product verification

3.4.1 Selection of samples for the products to be certified

For each homogeneous range of products covered by the certification application, ECM informs the "Manufacturer/Authorised Representative" of the number of units to be subjected to the activities and checks referred to in paragraph "2.1 - Certifiable Products, Applicable Procedures and Standards".

The "Manufacturer/Authorised Representative", when possible, must keep and make available for ECM the representative specimens of the product belonging to the various production batches placed on the market during the year or the previous verification by ECM.

The "Manufacturer/Authorised Representative" must communicate all the numbers of the available batches, including those not yet marketed.

The on-site verification of the samples is always preceded by the documentary analysis carried out by the personnel in charge of carrying out the evaluation activities of the certification process. The examination of the technical file by ECM takes place before any other field assessment of the product, the production process and the related controls carried out by the manufacturer for the product for which certification has been requested.

3.4.2 Audit Management

The objective of the verification carried out by ECM on the selected specimens is to verify compliance with all the requirements established by directives or regulations and standards, or technical specifications of reference.

Various types of test samples are to be checked at the CME headquarters, or, if necessary, field visits to the "Manufacturer/Authorised Representative" or to the final destination.

Once the documentary verification has been carried out on site, ECM evaluates whether to carry out the visit to the manufacturer or can agree with the manufacturer to send the samples to the ECM site.

The conformity verification process is indicated in the "**Product Certification Workflow (GDPR -WF)**" combined with the specific work-flows of the specific Directives/Regulations of the sector to which reference should be made (see attachments).

3.4.3 Outcome of the checks

The outcome of the checks and activities carried out by ECM is communicated to the "Manufacturer/Authorised Representative". If the sample(s) submitted does not comply with the standards or technical specifications, the tests may be repeated on a new sample.

The "Manufacturer/Authorised Representative" whose tests have been negative, must in any case provide evidence of the corrective actions taken in the face of the negative outcome of the first verification and present new products that comply with the necessary requirements.

€ The cost of the new checks will be borne by the "Manufacturer/Authorised Representative".

3.4.4 Multi-Site, Homogeneous Families and Takeover Management (IAF-MD1)

The following paragraph shall apply to the Directives referred to in paragraph "3.1 - REGULATORY AND LEGISLATIVE REFERENCES" with respect to the management of multi-site and homogeneous families. It does not apply to the PED with respect to the management of the takeover which is not provided for.

The days determined using the sizing tables must be calculated for each site subject to certification (calculate the verification times applicable to each site, as if they were independent organizations) and any reductions/increases in time must be applied for each individual site and not on the total number of days resulted.

The total time to be allocated for certification audits and surveillances is the total sum of the resulting time for each individual site plus the location and can never be less than what would have to be allocated if the activity were carried out at a single site (**see IAF-MD1** Guidance).

In addition, where a sampling approach is envisaged, the minimum audit duration for each sampled site should be determined taking into account the following aspects:

- on the basis of the number of employees employed in the activities of the directive it is analysing (FTE for QMS), the number of man-days is determined (**IAF-MD5 Guide Table Annex A, this table is applicable only to management system modules**);
- Adjustments to the theoretical duration are applied, taking into account the reduction factors and the applicable Risk Category and according to the relevant certification purpose for the site in question.

The table below summarizes the provisions of the document "IAF-MD1"

	Headquarters	Branch office x^n	
Certification	All the time	sample= √N	• N represents the total number of sites. The value found should always be rounded to the next integer. • Example: Organization with one operational headquarters and 58 production sites, the sample will be: • initial = √ 58 = 8 to which the head office must be added • surveillance = 0.6 x √ 58 = 5 plus the head office • renewal = 0.8 x √ 58 = 7 plus the head office • If activities are carried out in the N sites that can be traced back to several homogeneous types, the sample must be composed of the number of sites obtained from the subfamilies.
Surveillances	All the time	sample= 0.6 x √N	

Renewal	All the time	sample= 0.8 x √N	• Example: Organization with 3 types of activities carried out in N = N1 + N2 + N3 sites. • In the case of an initial audit, the sample will be = √ N1 + √ N2 + √ N3 to which the location must be added.

The choice of the sample of sites and the audit time assigned to each one must always be justified, with reference to the applicable requirements (**see IAF-MD1 and IAF-MD5 Guides**).

The takeover is in accordance with the provisions of the "**IAF-MD2 Guide for the Transfer of Accredited Certification of Management Systems**".

In general, inspections of production lines and plants, with reference to the directives subject to accreditation that provide for it, will be carried out as indicated in the following chapter "Audits concerning management systems" with the difference that only manufacturing activities relating to the product subject to certification will be taken into consideration.

Any other company activities, or company functions, involved in the production process will also be interviewed and evaluated solely from the point of view of the required certificate.

Particular emphasis will be placed on "end-of-line tests" and on the acquisition and management phases of the components and sub-assemblies necessary for the realization of the finished product (procurement, acceptance controls, final tests).

3.5 Certification process – Verification of the Manufacturer/Authorised Representative

3.5.1 Verification of the manufacturer's requirements for inspection modules

During the verification, the CME officers must be assisted by the manufacturer's personnel, who, moreover, must allow their access in safe conditions to all areas where activities relevant to the object of the certification are carried out, also for the interview of the personnel involved in the aforementioned activities.

The "Manufacturer/Authorised Representative" is required to promptly inform ECM if the following changes occur:

- legal, commercial, organizational status, or ownership;
- organization and/or management;
- changes to the product or production method;
- contact addresses and production sites;
- Important changes to the quality management system.

In general, the audit can also be based on interviews with personnel, through direct observation of the activities carried out, evaluation of workplaces, documents and records related to the production process.

The "Manufacturer/Authorised Representative" undertakes to provide CME representatives with all the necessary support for a correct assessment, ensuring in particular that the following are available:

- documents relating to the products and production process for which certification is required;
- records relating to the product under evaluation as well as system records related to the purpose, including reports of internal audits;
- the investigation of any complaints;
- information necessary for safe access to the production sites that will be subject to verification (see "5.4 - Occupational safety – disclosure obligation");
- any tools and procedures applied to maintain the minimum safety requirements set out in the directives/regulations.

The "Manufacturer/Authorised Representative" declares to accept the possible presence of an ACCREDIA Inspector and/or an Inspector representing the Competent Authority in accompaniment to the auditor and/or the CME operating technician in charge of carrying out the certification process when required.

The verification of the possession of the requirements provided for by the Regulations and by the Directives and/or Standards may involve both documentary examinations at the manufacturer's premises.

On-site verification is always carried out when a Quality System audit is scheduled.

If the documentation sent by the "Manufacturer/Authorised Representative" is not considered exhaustive, ECM may request an additional document, or arrange with the manufacturer an inspection visit in the field for the purpose of an in-depth analysis of the documentation itself.

The duration of the documentary examination and the field visit, in the case of a Quality System audit, is calculated in application of the "**IAF-MD5 Guide**".

€ The costs of the presence of these observatories are borne by ECM.

3.5.2 Audits of management systems

The certification audit is carried out in two phases, called stage 1 and stage 2, under the guidance of CME personnel suitably qualified as Lead Auditors.

The purpose and methods of execution of each phase of the audit are detailed in the audit plan that is sent to the organization well in advance of the date of execution of the activities.

Each audit includes the meeting:

- of openness, in which the objectives and methods of execution of the activity are defined, the applicable evaluation criteria, the confidentiality constraint to which the CME staff is subject;
- closing report, which communicates the outcome of the audit and the clarifications of the results, detailed in the report and in the list of findings, including;
- the methods and times for the resolution of the same.

During the activities, the inspection team proceeds to collect objective evidence through the examination of documents, direct observation of the activities, interviews with managers and operational staff, etc.

To this end, the assessors use the appropriate checklists that have already been prepared, which are to be considered a guide and not a binding document.

The team can therefore also carry out investigations not expressly provided for in the checklists.

Any external consultants of the client may participate in the audits at the latter's request, provided that they do not replace the company managers in the performance of their role.

In particular, the applicability of a Quality Plan is assessed before the audit is carried out.

This can be a document developed for the specific purpose, or it can be represented by a procedure or a set of management and operational documents that, as a whole, cover the requirements; moreover, the manual of the Organization's Quality Management System "QMS", if already present and specified in relation to the requirements of legislative and regulatory references, may be acceptable for the purpose.

If the assessment team finds that one or more requirements have not been met, it shall make a finding (see below). The complaint is immediately contested to the customer and treated as described in the next point.

The audits end with a final meeting, in which the inspection team presents the customer with a summary of the results of the audits.

3.5.2.1 Audit Phase 1

The Phase 1 Audit includes the verification of the descriptive documentation of the system and can be carried out both in ECM and at the customer's company (if necessary).

The purposes of this audit are:

- assess the suitability of the management system documentation in view of the requirements of the adopted standard(s);
- assess the location of the organisation and the specific conditions of the site(s);
- identify the applicable mandatory provisions and assess their compliance;
- initiate in-depth analysis, analysis and dialogue with the organization's staff, in order to determine the degree of application of the system;
- where required by the reference standard, assess whether internal audits and management review have been planned and carried out effectively;
- collect the information necessary to formulate the scope of the management system (processes and activities) and the site(s) subject to certification;
- review the necessary resources and agree with the organization on the details to perform the Phase 2 Audit;

- Provide clarification on the details of the certification process.

The findings, both documentary and operational, resulting from the audit are classified in the Terms and Definitions section.

Due to the presence of Non-conformities, the persistence of the same at the time of the Phase 2 Audit will prevent the issuance of the certificate and will make it necessary to carry out a post-audit.

For details on the management of surveys, see paragraph "6.4 - Classification and management of verification surveys". If, during the Phase 1 Audit, situations and conditions are found that are different from those declared by the Organization during the request for quotation phase, ECM reserves the right to notify the Organization of the need to revise the contractual conditions.

3.5.2.2 Audit Phase 2

The Phase 2 Audit must be carried out within 6 months of the Phase 1 Audit, otherwise ECM will assess the need to repeat the Phase 1 Audit completely or partially, possibly on a documentary basis.

The Phase 2 Audit is carried out at the Organization's site(s) and aims to ascertain the consistency of the defined policy with the related objectives in order to assess the effectiveness of the system both in accordance with the reference standard(s) and the documentation prepared.

During the Phase 2 Audit, the following is verified:

- the resolution of the findings that emerged in phase 1;
- information and evidence on compliance with all requirements of the standard(s) or other regulatory document applicable to the management system;
- monitoring, measuring, reporting and reviewing performance, with reference to defined objectives and targets;
- the management system and its performance, with reference to compliance with legal requirements;
- the methods of managing and keeping processes under control;
- internal audits and management reviews where required by the reference standard.

The findings, both documentary and operational, resulting from the Phase 2 Audit, will be classified according to their severity.

At the end of the Phase 2 Audit, the relevant report is delivered, possibly supplemented by the list of findings.

3.5.2.3 Surveillance Audits

Surveillance audits are intended to ensure that the organisation maintains an effective management system in accordance with the requirements of the reference standard(s) and the specific provisions established by the accreditation bodies.

The surveillance audit is mandatory and is based on a sampling of the activities subject to certification, ensuring the complete verification of the management system over the course of the certification cycle (usually every three years).

During these audits, the specific requirements of the harmonised standard and/or the reference directive relating to the products subject to certification are always checked.

During the surveillance audit, the effective implementation of the observations from the previous audit is verified.

CME carries out periodic surveillance audits on an annual basis (the first surveillance must be carried out within 12 months).

The reference date for planning surveillance audits is the last day of the phase 2 audit.

As a rule, no exceptions to the dates of execution of surveillance are applied except in the case of serious situations communicated in writing by the organization and evaluated and authorized by CME.

The performance of the surveillance audits provided for in the certification cycle is subject to the regular payment of the previous activities by the organization.

Otherwise, ECM reserves the right not to carry out the planned activities and proceed with the suspension of the certificate.

If the organization does not intend to perform the surveillance audit, it must promptly notify ECM in writing, which will proceed with the suspension of the certificate.

At the end of the surveillance audit, the relevant report is delivered, supplemented by the list of findings if necessary.

3.5.2.4 Renewal Audit

The purpose of the renewal audit is to ensure that the organisation maintains an effective management system in accordance with the requirements of the reference standard(s) and the specific provisions established by the accreditation bodies.

The renewal audit must be concluded, with a positive outcome, by the expiry of the certification, with reference to the date of issue of the certificate and the terms of validity indicated in the specific directives, in order to maintain its validity and historicity.

As a rule, no derogation is applied to the date of execution of the renewal unless limited to serious situations communicated in writing by the organization and evaluated and authorized by ECM.

If the Organization does not intend to renew the renewal, it must promptly notify CME in writing.

In this case, the certificate shall be suspended and the Organization shall immediately cease the use of the certificate and the certification mark.

Renewal made after the expiry date will be considered as a new certification, therefore the contractual conditions will have to be revised accordingly.

The performance of the renewal audit is subject to the regular payment of the previous activities by the organization, otherwise ECM reserves the right not to perform the activities required for the renewal audit. At the end of the renewal audit, the relevant report is delivered, possibly supplemented by the list of findings.

At the end of the renewal process, the provisions of the paragraph dedicated to the issuance of the certificate apply.

3.5.2.5 Additional visits or inspections at the decision of the Body

The "Manufacturer/Authorised Representative" must provide evidence of the positive or negative results of such tests, tests or surveillances and CME reserves the right to carry out additional inspections, always at the expense of the "Manufacturer/Authorised Representative", to verify the maintenance of conformity.

ECM reserves the right, with written justification to the Organization, to perform additional audits not included in the certification cycle. Audits can be:

- audits to lift the suspension of the certificate;
- scope change audits;
- in-depth analysis of the management of complaints received from the certified organization's customers;
- verification of the management system following the receipt of information on product recalls, serious accidents, injuries or malfunctions;
- verification of the implementation of the Corrective Actions opened as a result of major "Non-conformities".
- Audits at the request of market surveillance and surveillance authorities
- In the event that the CB has requested an additional verification for one of the aforementioned reasons and has already indicated dates and methods, the "Manufacturer/Authorised Representative" cannot fail to accept the execution by ECM subject to due coordination agreements. In case of refusal, the competent authorities will be notified.

€ The cost of these activities is borne by the Certified Organization.

3.5.3 Audit/Verification Report

At the end of the on-site verification, the CME officers compile a special evaluation report (hereinafter referred to as the "report"). Before finalizing this report, the audited organization shall:

- is informed of the result of the audit;
- has the opportunity to discuss the content of the report with the CME officers;
- Sign, for acknowledgment, the report delivery form, receiving a copy of it.

If ECM does not send to the "Manufacturer/Authorised Representative", within one week from the date of the visit, a written communication of correction of the findings contained in the report, the same shall be considered confirmed.

3.5.4 Non-Conformance Resolutions

The "Manufacturer/Authorised Representative" must undertake to eliminate any "non-conformities" detected during the aforementioned verification, by sending in writing the proposed corrective actions, accompanied by all the elements useful for the assessment by ECM of their suitability (the analysis of the causes that generated them, timing of implementation of the corrective actions and related responsibilities, documentary evidence, etc.)

In cases of particular seriousness or number of "non-conformities" detected, ECM reserves the right to carry out an additional inspection visit.

3.6 Issuance or issuance of certification

3.6.1 Issuance of certification

On the basis of the results of the checks carried out on the manufacturer (see "3.5 - Certification process – Verification of the Manufacturer/Authorised Representative") and the tests and verifications carried out on the products (see 3.4 - Certification process – Product verification") the ECM Certification Committee (CoC) decides whether or not to issue the certification.

Before issuing the resolution and issuing certification, the CoC carries out a review of the entire certification process (see "1.3.1 - CoC Certification Committee").

The outcome of the certification evaluation process is to be considered partial until the completion of the committee's resolution.

3.6.2 Deliberation

a) Positive resolution

In the event of a positive resolution by the Certification Committee, ECM will send the relevant Certificate to the "Manufacturer/Authorised Representative", who has thus become the concessionaire, in which the following are specified:

- the name and registered office of the organisation granting the certification,
- the production site(s) to which the certification refers,
- the product or the homogeneous range of products covered by the certification,
- the standard or technical specification of reference,
- conformity marks for which the use is granted,
- the date of issue,
- any further information, where required by regulatory provisions, accreditation, etc..
- The certificates are always signed by the Legal Representative of ECM.
- The delivery of the same is subject to the payment of the agreed amount for the verification activity performed.

b) Negative resolution

In the event of a negative resolution, the "Manufacturer/Authorised Representative" will be notified through the "Technical/Commercial Secretariat (UT/UFF COMM)" of the decision not to issue the certificate and the opening of "Non-Conformity (NC)". (See "7.7 - Rejection of certification").

Once all the NCs and the reasons that led to the refusal to issue the Certificate have been resolved, the "Manufacturer/Authorised Representative" may request a new assessment of the product provided that the revision carried out for the presentation of the new project is unequivocal; In this case, a new certification process will be carried out.

In the event that the NCs have not been resolved, the opinion of the CDC remains unfavourable to the issuance of the certificate. The "Manufacturer/Authorised Representative" will no longer be able to submit the application for the same type of project/product, except under another project name.

In the event of an unfavourable decision, the "Manufacturer/Authorised Representative" may appeal against the Resolution itself in accordance with the provisions of paragraph "13 - Reports, Complaints and Appeals".

In the event that the appeal is still unsuccessful:

- ECM informs the competent authorities "Accredia, Ministries, CIRCACB" about the certification practices it restricts, refuses, suspends, withdraws.

- Whatever the outcome of the tests and verifications carried out, ECM keeps the technical documents and the file of the file and the other documents attached to the application.

3.6.3 Validity of the certificate

The individual Directives/Regulations indicate the period of validity of the certificate issued.

Therefore, the period of validity of the certificate is defined according to what is indicated by the Directives/Regulations as the maximum period of use of the same, except for substantial changes made to the product itself, changes to Directives and Regulations and control procedures, in which case the certification expires immediately.

In general, the validity of the certification is also subject to the evolution of technological progress.

In particular, the following is specified:

- Validity of the certification issued with the procedure referred to in Module B: n years as established by the specific Product Directive;
- Validity of the certification issued with the procedure referred to in Form A2, C1, C2: annual, renewable following the execution of the required production checks;
- Validity of the certification issued with the procedure referred to in modules D, D1, E, E1, H, H1: renewable three-year term subject to the performance of the annual surveillance checks;
- Validity of the certificate issued with the procedure referred to in Form F and G: unlimited, except for substantial changes to the certified specimen.

The customer has the possibility to place on the market the products, the manufacture of which took place within the date of expiry of the validity of the certificate, within a period of 6 months from the date of expiry itself.

Products that are not in stock on the date of expiry of the validity of the certificate will no longer be able to bear the reference to the certification and, in the case of mandatory certification, will no longer be able to be placed on the market.

In such cases, ECM reserves the right to carry out an inspection visit to the customer's storage sites to verify the actual stock of the products in the warehouse on the expiry date of the certificate.

The certificate is no longer valid if the requirements of the directives, rules or regulations to which it was issued have been changed.

Similarly, the certificate is no longer valid when the manufacturer changes the product or production processes.

Further grounds for forfeiture of the validity of the certificate are specified in the relevant directives/regulations.

The validity of the certificate is subject not only to the continuation of the contractual relationship with CME, but also to the positive outcome of the surveillance activity referred to in the following article.

- ECM also has a permanent responsibility to ensure that the EC-type examination certificate remains valid. ECM informs the manufacturer of any significant changes in the regulations or internal procedures of the certification process that may have an impact on the validity of the certification certificate. ECM operates with all the necessary actions to implement the changes that affect the validity of the certification, starting, if necessary, from a new evaluation, review and decision process to the issuance of the official certification documentation/oversight activity under review. In the event of failure to comply with regulatory changes and/or CME regulations, it revokes the certificates that are no longer valid and informs the competent authorities of the certifications revoked by it. The decisions of the necessary revisions and revocation (also communicated to the competent bodies) are communicated to the "Manufacturer/Authorised Representative" by certified email or other method valid for legal purposes.
- ECM also informs the manufacturer of any finding and/or verification of incorrect transcription in the certified certificate of the date of issue, the index of the revision, period of validity or other, which had an implication on the validity of the certification certificate. The decisions of the revision are communicated to the "Manufacturer/Authorised Representative" by certified e-mail or other method valid for legal purposes. Decisions are also communicated to the competent bodies.

In the Notes section of the reissued certificate, it will say "Cancels and replaces certificate XXXX with incorrect transcription xxxxxxxxxx."

In the event of re-issuance of the certification, the "Manufacturer/Authorised Representative" undertakes to no longer use the replaced certificate and to return it to ECM.

3.6.4 Termination of the Agreement with ECM

The termination of the Contract with ECM, for any reason, relating to a valid certificate, maintains ECM's responsibilities under the directives and regulations, with regard to certified products. The certificate for which the termination of the contract has been requested shall expire on the expiry of the date indicated on the certificate.

- For QMS forms, ECM will ask the Customer for a declaration of the products and their factory numbers manufactured between the last surveillance and the date of the request for termination. ECM will proceed with an additional, onerous verification, during which the batches and products on which the CE mark has been applied and the number of the Body to register them will be verified, these products will be covered by the certificate.

The Client must inform ECM of the decision to terminate the contract by certified e-mail.

3.6.5 CME Database or List of Issued Certificates

Following the issuance of the certificate, the data relating to the certification issued are entered in the ECM database of certified products; further copies of the certificates issued, already issued by ECM to the "Manufacturer/Authorised Representative" and included in our. database, are available upon specific request of the "Manufacturer/Authorised Representative" with justification. From the ECM website it is also possible, by selecting "Certificates issued", to connect to the search platform for CE certificates issued by ECM and enter the protocol number of the certificate to be searched.

Copies of the certificates issued are made available to the accreditation and notification bodies to which the credentials to access the database have been provided.

ECM updates its list of certified customers with each new issuance or renewal of the certificate, and, where required by the applicable regulations for each product certification scheme.

The information made public (unless otherwise provided for by the relevant standards) is:

- Customer's company name;
- Status of validity of the certification;
- Reference standards and accreditation schemes;
- The site(s) covered by the certificate or the places of manufacture;
- Type of certified products, including clear identification of the certified product.

The above data may also be provided by ECM, upon request, to accreditation bodies, in relation to the status and type of accreditation and to anyone who makes a justified request.

On the ECM Website, in the Customer Service > Official Documents section > Certificate Search, you can check the validity of a certificate issued by ECM.

Anyone wishing to verify the validity of a certificate can do so through an Online Verification service, following the illustrated instructions on the site. In order to access the service, you must register.

If the online search does not give results, the user must send an email to info@entecerma.it attaching a copy of the document to be checked and their references.

The site also contains a list of invalid and/or counterfeit certificates identified by ECM.

3.6.6 Certificate Renewal

Renewal of the certification: in order to renew the validity of the certificate, if granted by the relevant legislation, it is necessary to carry out a new verification activity.

The consistency of this activity depends on the type of certification issued. For the renewal of certifications based on the application of a controlled management system, based on the applicable modules according to the Directive or Regulation.

For the renewal of certifications based on "type verification" and/or laboratory tests, it will be necessary to carry out a new evaluation of the product, including a new analysis of the documentation. ECM reserves the right to assess the extent of the verification to be carried out on a case-by-case basis, also on the basis of the complexity of the product, the manufacturing process or the potential hazard of the product itself.

The "Manufacturer/Authorised Representative" who is in possession of a certificate issued by ECM, close to the expiry of its validity as established by the Directives/Regulations, may request its renewal according to the following terms taking into account the following requirements:

ECM, which constantly updates the status of the certificates issued, notifies the certificate holders of the imminent expiry date with prior notice.

- ECM, 15 days before the expiry of the certificate, will send to the "Manufacturer/Authorised Representative" an offer for renewal which must in any case be accounted for even in the event of renunciation by the customer of the certificate, who has failed to send the notice as required by the previous paragraph:
  - the certificate will be cancelled upon expiry and its return will be requested and/or the obligation to cease use for the purposes previously permitted;
  - Any renewal (requested in advance or upon expiry) will result in the application of the commercial procedure provided for the evaluation of the products to be subject to certification, in accordance with the provisions of paragraph "3 - Certification Process".

In case of non-renewal of the CME Certificate, it will notify the competent Authorities via PEC of the expiry / withdrawal of the certificate.

3.6.7 Record-keeping

With reference to the Directives/Regulations, ECM keeps in its archives for a period of at least 15 years the documentation of the files filed or verified, unless the Regulations and/or Directives do not indicate longer periods.

The dossier must be kept at the disposal of the competent authorities for 10 (ten) years + 3 (three) years of recourse from the date of the last product placed on the market with valid certificates.

3.6.8 Manufacturer/Authorised Representative's obligations towards samples and prototypes

The "Manufacturer/Authorised Representative", in accordance with what is indicated in the offer/order, must adequately preserve and safeguard the certification issued by ECM for the entire duration of its validity, taking care of:

- keep the sample taken and identified by ECM, or the prototype tested at its premises, with appropriate marks or seals and make it available to ECM or the authorities at any time, only if it is not an assessment that involves the issuance of a certification for a product built in a single copy,
- or, if the prototype has an economic value of fundamental importance for the "Manufacturer/Authorised Representative", it must be decided between the parties whether ECM will not keep the specimen. To this end, it will be decided on a case-by-case basis how to proceed by formalizing it via email.

3.6.9 Procedure for the Filing of the Technical File (FT)

For certain directives/regulations, there is the procedure of simply depositing the FT in the ECM archives. For this particular activity, ECM only has the task of holding for a period of at least 10 years, with any extension requested by the customer for further years, to be sent by written request to the ECM sales secretariat.

The date on which the FT is taken over by ECM becomes the reference date for the calculation of the 10 years. The "Manufacturer/Authorised Representative" sends a written request to activate this procedure for its products/products to the ECM Sales Department.

ECM examines and evaluates the FT's filing request.

To this end, if it is accepted, an offer is prepared for the FT's deposit only for the period of 10 years.

If the customer accepts by signing the offer in all its parts, it will become an order / contract for ECM, which will require the application completed in its entirety according to the form provided, and the technical file must be sent together correctly closed in an envelope or envelope and identified, or by certified electronic format (PEC) with an opening key for the authorities who request to view it and to allow the verification of the legibility of said files to ECM.

- the verification of the applicability of the filing procedure is contextual to the signature of the review of the form "**Application for certification (QA07-17065_M04)**";
- the evidence of the confirmation of the filing procedure consists in the presence, directly on the envelope containing the Technical File, of the "date and signature" of the person who carried out the verification, as well as summary identification with all the available data.

In the case of electronic files, in the presence within the PEC of the form provided by ECM completed and signed by the customer.

- archiving of the Technical File for the number of years agreed upon during the order management phase;
- drafting of the FT Acknowledgement of Receipt;
- at the end of the filing period and in the absence of a request for extension by the Applicant, the envelopes of the relevant Technical Files are permanently deleted.

3.7 CME Accreditation – Suspension, Waiver and Revocation of Accreditation

3.7.1 As an Accredited Assessment Body

As a Conformity Assessment Body, ECM must be accredited by the Italian national accreditation body ACCREDIA, which is part of the EA, as according to **Regulation (EC) No. 765/2008** and the agreements with the notifying authorities, accreditation is an indispensable prerequisite for notification.

In particular, for the certification of products referred to in this Regulation, the accreditation of CMEs within the different schemes and sectors managed can be known at any time, by consulting the links in paragraph 1.1 of the Regulation.

3.7.2 Notification of suspension of accreditation

If the conditions are met, ECM will inform the "Manufacturer/Authorised Representative", the certification concessionaire, of any suspension, renunciation or revocation of its accreditation for the scheme of interest of the organization itself. ECM also notifies the competent authorities of any limitations, suspensions or withdrawal of the certificate.

3.7.3 Damage due to lack of accreditation

ECM is in no way responsible for any damage caused to the "Manufacturer/Authorised Representative" by the suspension, waiver or revocation of accreditation.

4 CONCESSION OF USE OF TRADEMARKS AND DISTINCTIVE SIGNS

4.1 Concession of use of trademarks

Starting from the date of issue of the certificate, the concessionaire has the right to use the marks granted by ECM, only with reference to the individual certification scheme or certification schemes for which it has obtained the relevant certification.

The CE marking, which indicates the conformity of a product, is the visible consequence of an entire process that includes conformity assessment in the broadest sense.

The general principles governing the CE marking are set out in the "**Regulation (EC) No. 765/2008**", while the specific directives regulate the affixing of the CE marking.

4.2 Provisions for the use of trademarks

The CE marking indicates that a product complies with the EU legislation to which it refers, and can therefore circulate freely within the European Single Market, or in non-European countries that recognize its validity.

By affixing the CE mark to a product, the manufacturer declares, under his sole responsibility, that it complies with all the requirements laid down in the legislation governing its affixing of the marking; as a result, the product can be sold throughout the European Economic Area (EEA).

4.2.1 Trademarks granted by ECM

The dealer may display on all certified products the marks granted by ECM with the relevant certification.

The licensee may also use these marks on material relating to certified products, such as advertising material and product packaging, subject to the following conditions:

- with the clear identification of the products covered by the certification,
- during the period of validity of the certificate,
- giving the correct meaning to the certification of which the marks are attested,
- without changes in shape (enlargements / reductions are allowed to allow perfect legibility),
- in any colours specified or in black and white;

- optionally, or where required by the regulations, by placing the number of the NB next to the CE marking;

If the EU Regulation provides, in accordance with Decision 768/2008, for a certification form for the quality assurance of product or production, total quality or other means under the supervision of a notified body, the CE mark, in the form and proportions provided, must be followed by the notification number of the body in charge of surveillance.

4.2.2 ACCREDIA Trademark

This trademark may optionally be used only by dealers in possession of certifications issued under accreditation, together with the mark granted by ECM and in compliance with the rules indicated **in the document "RG-09 – Regulations for the use of the ACCREDIA Mark (at the revision in force at the time of use of the same)"** which is intended to be fully referred to herein.

The ACCREDIA mark, under the terms and conditions set out in **Regulation RG-09**, can only be used for schemes for which ECM has obtained accreditation.

- This document is available on the http://www.accredia.it website.

4.3 Misuse of Marks and Certification

The use of trademarks, and certification, is incorrect if done in such a way as to mislead the recipients of the message or in any case in a way that does not comply with these Regulations.

In particular, by way of example, the use of the trademark and/or certification in association with the dealer's products is incorrect when:

- for products with an application for certification that has not yet been submitted or refused;
- the certification has not been issued;
- the certification has been suspended or revoked;
- during the period of validity of the certification, the dealer places on the market product models that have not been checked by ECM;
- the marks are combined with products not covered by certification;
- the marks are used in such a way as to be interpreted as marks of conformity to the standards of organizational management systems;
- when the Applicant has not implemented the changes requested by ECM.

4.3.1 Misuse of Marks and Certification – Actions Taken by ECM

- As soon as the incorrect use of the certification, certificate or CE marking is identified, ECM will take all appropriate measures to put an end to such use, while protecting its rights in the most appropriate ways, including by publishing the incident in its media and, where necessary, in the press.
- ECM, will notify the competent Authority and ACCREDIA, the Ministry, CIRCABC and will send a revocation to the Applicant of the right to affix the CE marking and to use the certification.
- In the most serious cases (e.g. undue marking) CME also informs the competent authorities.

4.3.2 Manufacturer's marks or markings

4.3.2.1 Manufacturer brand

The manufacturer's mark(s) must be displayed on the product in accordance with the requirements of the standards or technical specifications used for certification, as well as the "special requirements" (see Appropriate Marking Directive or Regulation)

4.3.2.2 Copy of CE plate

A copy of the manufacturer's mark(s) must be filed at ECM (copy of conformity marking as required by applicable directives).

4.3.2.3 Variation of recognition marks

In the event of a change in these identification signs, the "Manufacturer/Authorised Representative" must send ECM a copy of the new trademark or marks.

5 OBLIGATIONS OF THE MANUFACTURER/AUTHORISED REPRESENTATIVE

5.1 Obligations of the Manufacturer/Authorised Representative

The "Manufacturer/Authorised Representative" undertakes to:

(p.01) ensure continued compliance in accordance with point 2.2.02 of this Regulation.

(p.02) keep under control the activities and processes that affect the quality of the products according to the requirements established by the individual certification scheme or by the certification schemes for which it has obtained the relevant certification indicated in the certificates, with particular attention to the management of any complaints received from its customers;

(p.03) periodically and systematically check the certified production – directly or using third-party laboratories – in order to guarantee its constant compliance; in the case of internal tests aimed at keeping the relevant test and verification equipment in a state of efficiency and compliance with the consent of ECM; in the same way, in the case of the use of external laboratories, always with the consent of CME;

(p.04) communicate to ECM, in advance and in full terms, any changes it intends to make to a certified product; in this case, ECM reserves the right to accept the modification or to arrange for additional tests/verifications to be carried out, the cost of which is borne by the "Manufacturer/Authorised Representative", as well as to request the change of the type or model number reference

(p.05) notify ECM of any transfer of the production site indicated on the approval certificate, in this case ECM reserves the right to carry out further verification visits;

(p.06) provide the identification of the product, with the date and batch of production by applying the references suitable for tracing the origin of manufacture by means of the serial number or other coding system;

(p.07) if the product certified by ECM will be modified and placed on the market, it must have a different coding in order to avoid misunderstandings;

(p.08) absolutely avoid misunderstandings between its certified products and non-certified ones, on its catalogues or price lists and on propaganda in general, do not make any statement or advertise its certification in such a way that it could be considered misleading or unauthorised;

(p.09) not to use your certification in a manner that brings ECM into disrepute and not to make any statement regarding your product certification that ECM may consider misleading or unauthorized;

(p.10) take appropriate legal action against anyone who misuses the trademarks granted by ECM with its trademarks or markings and promptly informing ECM of events;

(p.11) keep a record of the complaints received and the related actions taken to remedy them, with regard to certified products, where required by ECM, give evidence of their management

(p.12) allow all ECM personnel in charge access to the production sites, including the staff of the Competent Authority and/or Notification, accompanied by the staff appointed by ECM; these situations, which are aimed at evaluating the work of the staff appointed by ECM, are regularly communicated with appropriate notice. Except in cases of rejection by the customer of individual assessors for justified reasons, any refusal by the concessionaire to accept the presence of the assessors of the accreditation body may result in the suspension or revocation of the certification, if it has already been issued;

(p.13) pay the amounts as established in the contractual agreements, for the maintenance of the certification, as well as for all the tests and verifications that are provided for a fee;

(p.14) allow and facilitate all the checks that ECM intends to carry out for the control of the certification issued, at the production sites concerned and in any case in the areas that are relevant to the certification itself;

(p.15) If you provide copies of the certification documents to others, the documents must be reproduced in their entirety or as specified in the certification scheme;

(p.16) Preserve and make available to ECM, the representative specimens of product belonging to different production batches placed on the market during the year or the previous verification by ECM;

(p.17) To keep and store the sample taken and identified by ECM, or the prototype tested at your premises, with appropriate markings or seals affixed by ECM, until the expiry date indicated on the sample (where applicable) or for a minimum period of 10 years when this is not indicated.

(p.18) If the customer carries out trials/tests at its own facilities, it must ensure that the test/test areas are "adequately suitable for carrying out the trials/tests", and must also ensure that "its personnel, in charge of the trials/tests" are suitable to carry out the activities;

5.2 Changing the Certification

If the concessionaire intends to change the scope of validity of the certification, it must make a written request to ECM, which will decide whether or not a new testing or verification activity is necessary. The costs related to this request are borne by the dealer himself.

5.3 Transferability of Certification

The certification is reserved for the organization or the "Manufacturer/Authorized Representative" and the areas mentioned in the certificate. It is not transferable, except in the case of transfer, transformation, merger, demerger, transfer of a particular branch of the organization concessionaire of the certification.

In these cases, the organization must send a communication to ECM in a timely manner, in any case no later than 15 days from the registration of the relevant registration in the Register of Companies, where applicable; Failure to comply with this deadline may result in the application of the measure suspending or revoking the certification.

In the cases described, the organization must submit to ECM a written request to maintain the certification of the person resulting from the change to the organizational structure, accompanied by a copy of the relevant certificate of registration with the Chamber of Commerce and any additional documents, if deemed necessary.

The "Manufacturer/Authorised Representative" who has acquired the rights of the transferor company will be obliged to accept these Regulations in their entirety and any contracts in place with ECM.

ECM will then ascertain, possibly also through additional tests/verifications, that the object of the certification has not undergone changes or in any case complies with the requirements of the reference standard or technical specification.

The costs of updating the certification and any tests/verifications will be borne by the organization resulting from the modification.

5.4 Occupational safety – disclosure obligation

In accordance with current legislation on safety and prevention of accidents at work, the "Manufacturer/Authorised Representative" undertakes to provide ECM with complete and detailed information relating to the specific risks existing in the work environment in which the personnel appointed by ECM are intended to operate.

The "Manufacturer/Authorised Representative" undertakes to promote cooperation and coordination for the purpose of implementing measures and interventions for the protection and prevention of risks at work.

In the case of "Manufacturers/Authorised Representatives" operating in countries outside the European Union, they will be obliged to comply with the requirements of the EU regulation.

6 CERTIFICATION SURVEILLANCE

6.1 Generality

ECM carries out periodic surveillance both on the manufacturer, to verify compliance with the requirements of this Regulation, and on certified products, to verify compliance with the requirements of the reference standards and technical specifications where it is obviously required.

Technical specifications may be taken into account in the absence of harmonised standards or national standards covering the risk not managed by approved standards. These specifications will be included in the FT submitted and approved by ECM.

This surveillance is carried out through inspections, tests and verifications, according to the criteria indicated in the following paragraphs of this regulation.

On the basis of the UNI **CEI EN ISO/IEC 17065 and UNI CEI EN ISO/IEC 17020 and ISO 9001 standards,** surveillance is carried out at least once a year for the certification of management systems or for product certifications based on total quality and/or approval of management systems.

ECM carries out surveillance activities, in all cases provided for by the applicable legislative framework, on an annual basis, unless otherwise specified in the contract.

The purpose of the surveillance audit is to check that the conditions that led to the granting of the certification are maintained, as well as any subsequent changes to the process or products.

For modules that provide for checks at random intervals, the surveillance, with a frequency of at least 1 time a year, can be increased according to particular situations detected in previous visits (e.g. scarcity of products to be checked, etc.).

As far as sampling is concerned, the same parameters defined in the dedicated Samples paragraph apply, with the precaution of changing the product tested within the family or range in order to cover the period of validity (where applicable).

In the case of modules that provide for the verification of management systems:

1. In the event of non-compliance, the company must send ECM the proposal for treatments and corrective actions within 10 days from the date of taking charge, while corrective actions must be implemented within 60 days from ECM's acceptance of the proposed corrective actions.

2. In the event that comments are issued, the company must communicate to ECM the corrective actions it intends to implement, it will be ECM's responsibility to verify their implementation during the next audit.

Once the maximum terms allowed have expired, upon decision of ECM, the certification may be suspended or revoked depending on the seriousness of the observations.

All organizations certified by ECM, for which surveillance activity is envisaged, are required to maintain a register of complaints received and to make it available to experts during the audit phase.

Planning and review dates are communicated at least 5 days in advance.

Surveillance shall apply where it is required by the applicable conformity assessment module/procedure.

6.2 Checks at the manufacturer's premises

6.2.1 Inspection visit to the manufacturer's premises

ECM carries out a surveillance inspection visit to the manufacturer of the certified products, at the established frequency at least once a year, or has the right to carry out surveillance visits without prior notice.

With regard to activities that involve the surveillance of PRODUCTION combined with PRODUCT TESTS, the surveillance at the manufacturer's point is carried out only by the ECM Technical Expert (ET).

With regard to activities that involve the verification of certified products and the Quality Management System and therefore the presence of a QMS auditor and an operating technician, who could be the same person if qualified and present in the CME registers, the planning of the surveillance activity is carried out according to the payment by the "Manufacturer/Authorised Representative" of the fixed fee for maintaining the certificate issued to which is added the calculated estimated cost in terms of man/time, depending on the number of products to be evaluated/kept under surveillance as required by the Tariff in force;

- for the QMS auditor according to the duration calculated in application of the "IAF-MD5 Guide" and provides that the checks are carried out in two phases (stage 1 + stage 2);
- per ET, calculated in terms of time/ET, depending on the number of products to be evaluated/kept under surveillance as required by the Tariff in force

The frequency of periodic annual inspections must allow a complete re-evaluation of the Quality System and production over a period of three years. The CME body may establish, depending on the production batches and the quantities of products to be sampled, more stringent procedures.

6.2.2 Unannounced audits

The need for additional and/or unannounced visits to the manufacturer and their frequency shall be determined on the basis of a control system on visits operated by ECM.

In particular, the following elements will be taken into account in the examination control system:

- the results of previous surveillance visits,
- the need to ensure the monitoring of corrective measures,
- where appropriate, the special conditions attached to the approval of the system,
- significant changes in the organisation of the manufacture, concerning technical measures or procedures.

During unannounced visits, CME may proceed with the collection of samples on which to carry out or have tests carried out, if necessary; among the documents issued, CME provides a report of the visit and possibly an audit report, but not the reports of any tests carried out.

6.2.3 Inspections in factories

The factories and warehouses and laboratories of the manufacturer and any suppliers must be open to CME representatives, who may appear – even unannounced – at any time during working hours.

6.2.4 CME Officers

The persons in charge of CME have the right to carry out all the checks they deem useful to check whether the manufacturer complies with the requirements of these Regulations, and in particular to view and possibly note the results of the tests carried out in accordance with the provisions of the paragraph "5.1 - Obligations of the Manufacturer/Authorised Representative. Clause p.03", as well as any complaints from third parties registered by the manufacturer. In the event of non-compliance with the certification requirements, the provisions of paragraph "7 - Waiver, Suspension, Revocation of Certification".

The manufacturer must allow and facilitate the checks of the CME representatives; They are required to limit interference with the manufacturer's business to the bare minimum.

6.2.5 Sampling

During the inspection visit, the CME representatives also have the right to take, at the plants or warehouses of the "Manufacturer/Authorised Representative", a sample of the certified products and/or its parts, to verify the conformity of the production and the homogeneity of the product with the requirements of the reference standards or technical specifications.

The "Manufacturer/Authorised Representative" will make available to ECM the samples required for the execution of the relevant checks as required by the certificate surveillance procedure.

6.2.6 Full visualization of procedures

ECM makes available on request, only to customers who have signed a contract for CE Certification, the complete view of the specific procedures relating to the Directives/Regulations applied for product evaluation procedures.

The request must be sent by the "Manufacturer/Authorised Representative" by certified e-mail and to the sales representative who drafted and sent the offer in order to make arrangements on how to access the CME procedures, which will always take place at the headquarters of the Body under the supervision of an internal representative.

6.2.7 Mandatory monitoring of production

In the event that it is not possible to carry out the manufacturing control for a given category of certified products for a period of at least one year, ECM will require that the "Manufacturer/Authorised Representative" issue a written declaration informing ECM of the reasons why it is unable to subject production to mandatory surveillance, before suspending the certifications issued.

This can be the following reasons:

- Temporary unavailability of production due to a particular economic situation that the "Manufacturer/Authorised Representative" had not been able to foresee and which did not allow him to be able to maintain the usual quantitative production standards or a sufficient number of products to be able to subject the series to ECM surveillance.
- The production is available but the "Manufacturer/Agent" chooses to withdraw from the contract earlier than the expected duration by giving written notice and justifying the reasons, specifying that he has appointed another CB to take care of the surveillance

6.3 ECM Control Tests

ECM carries out tests on the samples taken at its own laboratories or at those of the manufacturer or at accredited laboratories chosen directly by the manufacturer, chosen according to the criteria of the necessary tests to be carried out, in whole or in part, to ascertain their compliance with the reference standards or technical specifications.

These tests will be carried out in accordance with the plans and criteria prepared for this purpose by the Technical Office and specified in the particular requirements of the sector.

Tests carried out by the CME Laboratory (**Accreditation No. 1515 L**) on products that fall within the categories of accredited tests subject to EU Type Examination, delivered and sampling that is required in application of the Directives and or Regulations in question, are accepted.

The "Manufacturer/Authorised Representative" will make available to ECM the samples required for the execution of the relevant checks as required by the certificate surveillance procedure.

6.4 Classification and management of verification surveys

6.4.1 Product non-conformities

The CN may give rise to the adoption of one of the sanctioning measures referred to in paragraph "7 - Waiver, Suspension, Revocation of Certification".

Non-compliance may result in the adoption of one of the measures suspending the certification process, revocation of certification. Non-compliance is a lack of a Directive requirement that affects the manufacturer's ability to ensure the conformity of the Product with the conformity requirements for obtaining and/or maintaining certification, the safety of the user, the safety of the product and/or the integrity of the Quality System;

€ All costs related to the review shall be borne by the manufacturer.

6.4.2 Product Comments

The survey formalized as OBSERVATION (OSS) does not give rise to the adoption of an immediate measure (suspension of the certification process, revocation of certification), but must be taken in charge and processed, If not processed it is reclassified as Non-conformity. It is caused by minor deficiencies that do not affect the manufacturer's ability to ensure the compliance of the Product with the compliance requirements for obtaining and/or maintaining certification.

6.4.3 Product Comment

The finding formalized as a COMMENT does not give rise to the adoption of a measure, it is determined by a report provided to the "Manufacturer/Authorized Representative" to focus his attention on certain topics for which there is a risk of deficiencies.

6.4.4 Survey management

CME requires evidence of the taking charge of Non-Conformities and Observations, which must be provided no later than 10 days from the date of reporting of the findings. The maximum time limit for the resolution of the findings is 60 days. After 60 days, the suspension is provided and the report is provided to the Notification Authorities and Notified Bodies whose conformity assessment activities are similar and cover the specific directives.

7 WAIVER, SUSPENSION, REVOCATION OF CERTIFICATION

7.1 Waiver of certification

The "Manufacturer/Authorised Representative" may request waiver of the certification, at any time of the ITER, by means of a written request. The waiver may be linked to internal problems of the manufacturer.
In the event that the Manufacturer renounces the certification with a written request, it is not entitled to reservations, also because the decision to renounce is not dictated by ECM.
The interruption measure is communicated to all the authorities concerned, and to the Notified Bodies whose conformity assessment activities are similar and cover the same CME Directives.
In this case, the deposit paid or any total amount will not be refunded to the Manufacturer.

The "Manufacturer/Authorised Representative" may waive the certification:

The manufacturer may request the waiver of the certification, in the case of multi-year validity, by means of a written request to be sent within 3 months from the date of expiry or within 2 months from the date of execution of the annual surveillance.

After these deadlines, it is always possible to waive the certification, however the manufacturer is required to pay an amount equal to 40% of the price established in the tariff for carrying out the inspection, if the verification has already been planned by the Body.

In case of renunciation, the manufacturer is obliged to stop using the certificate issued by ECM and to suspend the marketing of products marked under this certification starting from the date agreed with ECM.

The waiver will be communicated by ECM to the competent authorities.

a) in the event of withdrawal;

b) for some models included in a certificate of approval or for all of them, with thirty days' notice with respect to the dates of invoicing of the maintenance fees, indicated in the CME Fee Schedule;

c) when it does not intend to adapt to changes in the reference standards/technical specifications (see "8.1 - Amendment or repeal of reference standards or technical specifications");

d) when you do not accept the changes made to this Regulation and/or to the related particular requirements for products subsequent to the entry into force of the new Regulation (see "8.2 - Amendments to this Regulation");

(e) when you do not accept changes in the tariffs relating to the annual maintenance fees for the certification (see "9.2 - Variation of the CME Tariff");

f) in the event of renunciation or revocation of the accreditation of CME for certification according to the scheme of interest.

The waiver must be communicated by email or other method valid for legal purposes.

If all certificates associated with a given Certification Agreement have been cancelled, the "Manufacturer/Authorised Representative" may:

- withdraw from the contract as indicated in paragraph "11.2 - Withdrawal from the contract";
- Keep the contract active.

In this second case, ECM will continue to carry out the surveillance activity referred to in paragraph "6.2 - Checks at the manufacturer's premises", in accordance with the procedures that take into account the specific situation and with the application of the costs specified in the CME Tariff.

The "Manufacturer/Authorised Representative" may renounce the certification only before the start of the certification process or before the official application has been submitted.

The waiver is to be considered in force from the moment ECM receives the communication from the "Manufacturer/Authorised Representative" with the reasons before starting the certification process.

7.2 Consequences of the renunciation of the certification obtained

In the event of renunciation of the certification obtained, the "Manufacturer/Authorised Representative" undertakes to:

(a) cease to affix the certification mark to the products concerned and not to increase their production during any notice period;

b) communicate within thirty days from the date of the renunciation, that there are no stocks of the certified product in the establishments or warehouses concerned. In the case of stocks of products under surveillance, the body that will have to carry out the checks must be communicated to ECM;

c) remove from products, catalogues and all documents, the mark relating to the certification, as well as any reference to the certification itself;

d) in the event of withdrawal from the certification contract, pay the balance of all amounts due to ECM.

ECM, in turn, provides:
aa) interrupt the control activity referred to in art. 6 above;

bb) cancel the certification of the products and inform the competent bodies.

cc) Carry out an extraordinary check to check any batches in stock, the costs will be borne by the Customer.

7.3 Suspension of certification

A product certification may be suspended in the event of situations which may jeopardise the conformity of the product with the relevant Directive, subject to a decision of the Certification Committee.

The suspension has a defined duration and entails the suspension of the validity of the certificate already issued.

In this case, the organization loses the right to refer to this certification.
Certification may be suspended when ECM has reason to believe that the certified product no longer meets the legislative, legislative and/or regulatory requirements and, in particular, in the following cases:

- non-fulfilment by the "Manufacturer/Authorised Representative" of the obligations set forth in art. 5 above;
- detection of serious or high-number non-conformities; failure to take corrective action and, in general, negative outcome of surveillance audits.

- impossibility to carry out surveillance visits according to the indicated time intervals
- at the reasoned request of the Organization (such as company crises, suspensions of the production of the certified product);
- In exceptional cases, and only once during the Certification period, the Organization may request, for a short period, the suspension of the Certification; The decision shall be submitted to the Resolution Committee.
- In the event of suspension of the production of the certified product, the Organization may request the suspension up to a maximum of 12 months.
- In the event of impossibility to resume production and in the absence of specific waiver by the Organization, ECM will order the revocation of the Certification
- in the event of non-payment of fees due to CME, for any reason,
- serious non-compliance with this Regulation;
- manufacture of the product with deficiencies in compliance with the essential requirements of the relevant directive;
- manufacture of the product with characteristics different from the approved type;
- production process without adequate and/or documented internal control to ensure that mass production conforms to the approved type;
- complaint from the field and/or intervention of the regulatory authority for manifest non-compliance of the product with the essential safety requirements of the relevant directive;
- non-conformities in the management system, not resolved within the established timeframe;
- failure to communicate changes to the product/process or management system;
- failure to communicate judicial measures, or serious irregularities related to the certified system;
- failure to communicate a change in the company name or the relocation of the production site;
- refusal by the manufacturer to provide the sample(s) necessary for the repetition of tests and conformity checks;
- refusal by the manufacturer to access the production site and/or the relevant technical documentation, for CME staff and/or experts of the accreditation body (where applicable);
- changes have occurred to the mandatory standards or legislation applicable to the product, to which the manufacturer cannot or does not want to comply within the timeframe provided for by the new legislation;
- repeated non-payment of certification fees, in whole or in part.

The suspension of the certification may be notified to the manufacturer by registered mail with return receipt, certified e-mail.

The notification will contain the reasons for the suspension and the deadlines for any corrective actions.

ECM will communicate the suspension of certification to the Notification Authorities and Notified Bodies whose conformity assessment activities are similar and cover the specific directives.

All records and evidence collected will be submitted to the certification committee which will decide whether to withdraw the suspension, continue it or revoke the certification.

€ The costs incurred by CME for this additional activity shall be borne by the manufacturer in accordance with the terms and conditions of payment provided for in this Regulation.

7.4 Consequences of Suspension of Certification

7.4.1 During the period of suspension of certification, the manufacturer shall

- is required to suspend the production and supply to the market of the certified products subject to the suspension;
- may not use the certificate and marks referred to in Chapter "4 - Concession of Use of Trademarks and Distinctive Signs", nor qualify as a Certification Concessionaire Organization;
- however, it is required to pay the amounts for the maintenance of the supervision of the certification.
- segregate and identify as non-compliant any products already in stock and withdraw any products already placed on the market, if the suspension derives from technical problems;
- do not use the notification number in conjunction with the product with suspended certification for the duration of the suspension;
- not to advertise the certification that is no longer valid;
- In the event that the products have already been placed on the market, and it is not possible to have products checked by ECM, for these products, equivalent extraordinary procedures for control must be agreed.

With regard to the timing of the resolution of the non-conformities that led to the suspension, the following timelines apply:

- treatment: it must be implemented as soon as possible;
- communication of the proposed corrective action no later than 15 working days from the notification of the suspension, except in cases of immediate danger to end users;
- implementation of the corrective action: maximum of 60 working days from the acceptance by ECM of the proposed corrective actions.

ECM in turn:

- may suspend the surveillance activity referred to in paragraph "6 - Certification Surveillance";
- communicates the suspension measure to the Entities concerned.

7.4.2 The suspension may only be lifted if the concessionaire has remedied the

To the findings made, adopting the appropriate corrective actions and demonstrating, moreover, that it has taken those preventive actions aimed at avoiding the recurrence of the non-compliance within the time and within the established terms.

The manufacturer who believes that he has resolved the non-conformities detected can request an inspection in a shorter time than that provided for by ECM which, compatibly with its internal planning, will appoint the verification team with the standard methods and costs. In this case, the deadline of 60 working days may be waived upon written notice from ECM.

Before proceeding with the reinstatement of the certification, ECM may carry out examinations, tests, documentary checks and/or at the Organizations concerned, in order to ascertain the effective resolution of the problems previously encountered.

€ All costs related to these additional checks shall be borne by the manufacturer.

7.4.3 Suspension Measures

Suspension measures have a maximum duration of 6 months. After this period, in the absence of the restoration of compliance, the certification is revoked. A period of 6 months is provided as it is considered an appropriate period to allow the manufacturer to order the adoption of appropriate Corrective Actions in the event of Non-Compliance.

The Management of ECM may also order the suspension of the certification in the event that the payment of the fees due to ECM is delayed by more than 60 days with respect to the date provided for in the contractual conditions (payment date indicated on the invoice), despite the reminder sent by ECM at the end of the 45th day of delay. This is without prejudice to any agreements for deferral of payments, which must be authorized by the Management of ECM.

If the "Manufacturer/Authorised Representative" persists in its non-compliance due to non-payment of the sums due, after a further 30 days to the 60 days of delay and suspension, the certification is automatically revoked by the ECM Presidency.

The measure of suspension of the certification and any reinstatement measure are communicated to the "Manufacturer/Authorised Representative" by certified email or other valid method for legal purposes.

7.5 Revocation of certification

ECM may revoke the certification in the event that the reasons that led to the suspension of the certificate have not been resolved, or proceed with the immediate revocation in the following cases:

- serious non-compliance of the certified product or management system, such as to jeopardise compliance with the essential safety requirements of the applicable directive or legislation;
- misleading use of the certification, notification number such as to bring CME into disrepute
- The certification may also be revoked following an explicit request for renunciation by the manufacturer, in the event of cessation of production of the certified product or in the event of transfer to another body.

The certification may be revoked due to non-compliance of the "Manufacturer/Authorised Representative" with the Certification Contract and in particular, in the event of:

a) bankruptcy or cessation of the activity of the "Manufacturer/Authorised Representative";

(b) failure to comply with the commitments given in paragraphs (b) resulting in gross negligence "5.1 - Obligations of the Manufacturer/Authorised Representative" and "6 - Certification Surveillance";

(c) serious irregularities or abuses in the use of the certificate and/or mark;

(d) civil and criminal conviction of the manufacturer for failure to comply with the mandatory requirements of the product covered by the certification;

e) failure to comply with changes in laws and/or directives/regulations;

(f) failure to cancel the suspension of the certification, in accordance with the provisions of paragraph "7.4 - Consequences of Suspension of Certification".

The withdrawal of certification for technical reasons shall be decided by the certification committee which approved it and shall be notified to the manufacturer by registered mail with return receipt, certified e-mail. The letter will contain the reasons for the revocation.

ECM will communicate the revocation of the certification to the Notification Authorities and Notified Bodies whose conformity assessment activities are similar and cover the specific directives.

The body has the right to be aware of the serial numbers and numbers of batches not yet marketed or in the process of being marketed by the customer who have a certification revoked (see "3.4 Certification process – Product verification").

7.6 Consequence of revocation of certification

In the event of revocation of the certification, the "Manufacturer/Authorised Representative" undertakes to:

- return to ECM the originals of the CE/EU Certifications obtained;
- no longer use the certificate and the mark(s) granted for use;
- not to use copies and/or reproductions of the withdrawn certificate;
- not to advertise and use revoked CE/EU Certifications, removing the logo and references to ECM from the documentation in use;
- cease to affix the CE marking to products referable to the revoked CE/EU Certification and, consequently, cease to market them
- remove from all products (including those in stock), catalogues and all documents called trademarks, as well as any reference to the certification itself;
- pay the balance of all amounts due to ECM.

ECM, in turn, provides:

(a) stop the surveillance activity referred to in paragraph "6 - Certification Surveillance";

(b) indicate the withdrawal of the product certification in the database referred to in paragraph "7.5 - Revocation of certification";

(c) notify the competent authorities concerned of the revocation order.

7.7 Rejection of certification

In the event of evidence of serious non-conformities that emerged during the assessment phases, ECM reserves the right to refuse the certification of the product in question, based on evidence that has emerged.

After examination and confirmation, the certification committee will activate a process to manage the rejection of certification; The decision will be made known to the applicant, motivated and documented.

ECM will communicate the refusal of certification to the Notification Authorities and Notified Bodies whose conformity assessment activities are similar and cover the specific directives.

7.8 Consequence of refusal to issue the certification

In the event of refusal to issue the certification, the "Manufacturer/Authorised Representative" undertakes to:

- not to submit a request for certification for the same product to another Notified Body;
- in the event that it is still necessary to request the certification of the same product, to evaluate the correction of the project / product / system according to the NC found and to propose and agree with the NB the most suitable system to resolve the NC on the product or system of the organization

7.9 Special requirements

7.9.1 Request by an organization to transfer its certificate from another ON to ECM and vice versa

ECM does not accept product certification transfers unless certain parameters have been evaluated.

For modules that require quality assurance-based compliance:

A) if the Organization decides to transfer its certification from a Certification Body to CME, the following procedures shall apply, defined in accordance with the **IAF-MD2 Guide**.

If the transferor CB's accreditation has been suspended or revoked, the transfer must be carried out at the customer's premises (within 6 months of the suspension or revocation or by the expiry date of the certificate whichever occurs earlier) and must last a minimum of 1 day in the case of suspension and a minimum of 2 days in the case of revocation. If the certificate to be transferred is suspended, a new certification process must be carried out.

In order to verify the admissibility of the certification being transferred and carry out a pre-transfer review, Ente Certificazione Macchine must verify and have:

- confirmation that the client's certification falls within the accredited scope of the issuing and accepting certification body;
- confirmation that the accredited scope of the issuance certificate falls within the scope of your accreditation body's MLA (Multilateral Agreement).

In addition, the applicant must provide:

- the reasons for the request,
- the sending of the original certificate of the Organization;
- the first certification report(s) the most recent certification audit reports and the latest surveillance report;
- the status of any outstanding non-conformities that may arise from them and any other available and relevant documentation related to the certification process.

If such audit reports are not made available or if the surveillance audit or recertification audit has not been completed as required by the issuing certification body's audit program, the organization will be treated as a new customer;

- complaints received and actions taken;
- relevant considerations for establishing an audit plan and audit programme;
- any current engagement by the transferring client with regulatory bodies relevant to certification in relation to legal compliance.

ECM will not issue the certification to the transferring customer until:

- will have verified the implementation of corrections and corrective actions for all outstanding non-conformities; and
- Accepted the transferring client's correction plans for all outstanding observations.

Where the pre-transfer review (desk review and/or pre-transfer visit) identifies issues that prevent the completion of the transfer, ECM will consider the transferring client as a new client.

The justification for this action will be explained to the transferring customer.

If the pre-transfer review does not identify any problems, ECM assesses whether it is necessary to perform a pre-transfer visit in the field before the certification is issued or whether the documentary evidence sent by the Organization is sufficient to issue the certificate, a decision that will be communicated to the Client.

Following a positive resolution of the Resolution Committee, the certificate will be issued to the Organization, which will maintain the expiry date of the original one, unless it has been a new issue.

The issued certificate must bear the date of first issue (by the transferring CB) with a note specifying that the first issue was made by another CB, the date of the transfer, and must maintain the original expiry date and surveillance periodicities of the original certificate.

When transferring a certificate, the purpose of the certificate should not be changed.

B) if the Organization decides to transfer its certification from ECM to another Certification Body, the following procedures shall apply, defined in accordance with the IAF-MD2 Guide.

ECM will give its maximum support to facilitate the transfer of all the necessary documentation to facilitate the other ON and the organization, highlighting everything provided without hindering the process.

ECM reserves the right to activate this collaboration procedure only if the organization has fully fulfilled the payment of what was previously established and agreed with ECM.

8 MODIFICATION OR REPEAL OF THE REFERENCE STANDARDS/TECHNICAL SPECIFICATIONS – AMENDMENTS TO THE REGULATION

8.1 Amendment or repeal of reference standards or technical specifications

Should the Directive, the standard and/or the technical specifications of reference be modified or repealed, ECM will promptly notify the "Manufacturer/Authorised Representative".

The "Manufacturer/Authorised Representative" will have the right to adapt the product to the new requirements within the deadline indicated by ECM, or to renounce the certification.

In the event that the "Manufacturer/Authorised Representative" decides to maintain the certification, ECM will verify the compliance of the product with the new regulatory requirements.

€ The costs for the aforementioned verification will be communicated in advance by ECM, for the purpose of their acceptance, and will be borne by the "Manufacturer/Authorised Representative".

Certified organizations have the right to accept or reject the decisions made by ECM; In the latter case, the certification is revoked, in the manner described above.

In case of acceptance of the changes, ECM reserves the right to verify the implementation of the necessary adjustments to the new requirements.

In particular, if the new requirements concern the product, ECM verifies the compliance of the Organization's certified product with the new regulatory requirements.

The positive outcome of this verification gives rise to the issuance of a new certificate of conformity and a new user license.

The Organization must include the new certificate number on the declaration of conformity for the product and, below it, with the same characters and dimensions, a wording indicating the updated edition of the standard/scheme/standard applied.

€ The costs of any additional visits shall be borne by the requesting Organization.

Compliance with this requirement applies to all existing certifications.

In the event of renunciation or in any case failure to complete the certification update process, ECM will proceed with the cancellation of the relevant certificate as it is no longer valid and the information to the competent bodies.

8.2 Amendments to this Regulation

In the event that ECM makes changes to the requirements of these Regulations that may have an impact on the "Manufacturer/Authorised Representative" or that require acceptance by the applicant or concessionaire of the certification by the "Manufacturer/Authorised Representative", ECM will give advance notice by e-mail and communication by certified email, with simultaneous publication on its website. ECM will keep evidence of the transmission to the "Manufacturer/Authorised Representative".

If the "Manufacturer/Authorised Representative" does not respond by e-mail or certified e-mail within 5 working days of receipt of the notification of the change to the Regulations, the relevant amendments will be considered tacitly accepted.

9 RATES

9.1 Amounts and fees for maintaining and supervising certification

The amounts relating to certification activities and maintenance fees, as well as the related payment conditions, are usually indicated in the offer/contract, documents drawn up according to the rates indicated in the CME Tariff in force and on the basis of the information provided by the Organization.

€ For anything not expressly provided for in the offer/contract, as well as in the absence of the same, the amounts indicated in the ECM Tariff in force shall apply, where the amount is not provided for, a minimum hourly rate is defined or a final price is established.

What is reported in the offer may be subject to change, due to changes / updates to the tariff or following review of the order in the event that variations are found with respect to what was received with the request.

Variations may result from:

- Manufacturer's request following changes to the product/system subject to certification;
- Examination of technical/system documentation;
- On-site audit;

9.2 Variation of the CME Tariff

The tariff is implemented by the Certification Body and is approved by the Legal Representative.

The provisions of the tariff may be subject to a discount policy decided by the Sales Department and/or the Legal Representative.

The tariff is also submitted to the Committee for the Safeguarding of Impartiality (C.S.I.) to guarantee the correctness of ECM's work and the absence of discrimination against all potential customers.

Any changes to the CME Tariff relating to the annual fees for maintaining the certification will be communicated to all the organizations that are certification concessionaires or that are in the process of obtaining and maintaining it.

In any case, the changes will only affect activities that have not yet been carried out.

The "Manufacturer/Authorised Representative" has the right to renounce the certification within one month from the date of receipt of the communication relating to such changes; In the absence of waiver, the changes are considered accepted.

The "Manufacturer/Authorised Representative" who avails himself of the aforementioned right of waiver shall be charged the rates prior to the changes, up to the date of termination of the relationship.

9.3 Terms of payment

As a general indication, in each offer there is the payment of a deposit specified in the offer, at the time of submission of the application for certification, following the acceptance of the estimate, while the balance must be paid in order to receive the certificate.

The charges will be paid against the relevant invoice.

Different conditions may be decided by the Sales Department and/or the Legal Representative, on the basis of historical data of the applicant's reliability.

Where the Directive or the certification scheme provides for regular monitoring, a tender will be prepared containing the timing and deadlines for carrying out the inspections as well as the related remuneration.

The cost relating to the surveillance activity must be paid upon completion of the same and against the relevant invoice.

10 CERTIFICATION LIMITS AND RESPONSIBILITIES

10.1 Legal obligations and mandatory requirements – Manufacturer's/authorised representative's liability – Indemnity

(p.01) The issuance and maintenance of product certification does not constitute a guarantee by ECM of compliance with legal obligations and mandatory requirements incumbent on the "Manufacturer/Authorised Representative".

Therefore, the "Manufacturer/Authorised Representative" remains solely responsible for civil and criminal liability, both towards themselves and third parties, for the correct performance of its processes and the compliance of its products with the relevant mandatory requirements, such as laws, directives, regulations, etc., of an international, national or local nature, as well as with the expectations of customers and third parties in general.

(p.02) The "Manufacturer/Authorised Representative" also undertakes to indemnify and hold harmless ECM and its employees, auxiliaries and collaborators from any claim, action and/or claim made by anyone in relation to accidents and/or damage to third parties related to the activities carried out by ECM on the basis of these Regulations.

(p.03) The "Manufacturer/Authorised Representative" is in any case obliged to take out insurance on the product subject to certification for civil and criminal liabilities deriving from the use of the same, which covers any defect in the use of the product also by ECM during the checks.

10.2 CME Default – Limits to Liability

Except in the case of wilful misconduct or gross negligence, ECM's liability towards the Organization that requested the certification, for any damage that may arise from the execution or partial non-fulfillment of the obligations covered by the certification contract, will be limited to the maximum amount of 2 (two) times the compensation due and actually received for the assessment activity carried out at the time of the error and/or omission that caused the damage.

10.3 Forfeiture clause

Any complaint or request for compensation against ECM must be made by the "Manufacturer/Authorised Representative", under penalty of forfeiture, no later than one year from the event that gave rise to the request or complaint.

11 DURATION OF THE CERTIFICATION AGREEMENT

11.1 Contract

The Contract (see "3.2.2 - Submission of the Offer - Contract), of which these Regulations are an integral and substantial part, is stipulated according to each explicit request, and takes effect from the date of acceptance by the "Manufacturer/Authorised Representative" of the offer made by ECM or from the submission of the first application for product certification.

The duration of the contract between ECM and the "Manufacturer/Authorised Representative" is established according to the duration of validity of the certificates, as prescribed by the applicable Directives/Regulations.

11.2 Withdrawal from the contract

The "Manufacturer/Authorised Representative" may withdraw from the Contract stipulated with thirty (30) days' notice, by certified email or other method valid for legal purposes only before the certification process has begun.

- After this date, the client is required to pay the amount agreed in the contract.

11.3 Validity of the contract

In the event of withdrawal by the "Manufacturer/Authorised Representative", all the provisions of these Regulations that are functional to the maintenance of the products in compliance with the standard and the technical specifications of reference remain valid for the remaining period of validity of the contract, with particular regard to the right of ECM to carry out checks and obtain information if it has reason to believe that such conformity has failed. During this period, all the fees agreed for the activities carried out by the same up to the effective date of the withdrawal will also be due to ECM.

12 PROCESSING OF PERSONAL DATA AND CONFIDENTIALITY

The information is provided to those who work with ECM pursuant to Article 13 of Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

The Data Controller is ECM S.r.l, with registered office in Castello di Serravalle (BO) via Cà Bella 243/A 40053 Valsamoggia, in the person of the Legal Representative Mr. Luca Bedonni.

12.1 Confidentiality Commitment

All documents relating to the application for certification and the evaluation of processes and products (documentation, records, communications, test reports, etc.) are considered confidential, except as provided for in the context of mutual recognition agreements (MLA) to which ECM adheres and vis-à-vis the ACCREDIA Accreditation Body. Access to and consultation of the documents relating to the certification are reserved only for CME personnel involved in the certification process. In the event that information relating to the process or product of a "Manufacturer/Authorised Representative" must be communicated or disclosed due to legal obligations, ECM will give written notice to the applicant, for example if a consumer submits a complaint (see "13 - Reports, Complaints and Appeals"). In the case of information requested by the

authorities for the purposes of judicial investigations, where the offence of disclosure of official secrecy may be committed, (Article 326 of the Criminal Code) This clause shall be deemed not to be applicable, unless verified by the authority itself.

ECM provides information on the validity status of the certificates issued to anyone who specifically requests it.

12.2 Place of data processing

The personal data (hereinafter referred to as "the data") provided directly by the Client or through third parties, are and will be processed by ECM – and in particular recorded and stored in a database – in order to ensure the proper performance of contractual relations with the Client, both on a legal level (e.g. fulfilment of accounting, tax, etc.) and commercially (e.g. for sending your own catalogues, brochures, etc.).

The data connected to the services of ECM s.r.l. take place at the registered office of ECM in Castello di Serravalle (BO) via Cà Bella 243/A 40053 Valsamoggia, and are handled only by ECM personnel responsible for data management or by any external collaborators for the maintenance of the database itself.

Under no circumstances is the transfer of personal data to a third country or to another international organization "**Regulation 2016/679 art.13 paragraph 1 point f)**".

12.3 Purpose, legal basis of data processing and type of data processed

The collection and processing of your personal data is carried out for:

- the performance of the contractual or pre-contractual relationship (legal basis: performance of a contract or pre-contractual measures)
- the performance of the services provided for in the contract, and in particular the issuance, waiver, suspension or revocation of the certification."7 - Waiver, Suspension, Revocation of Certification").
- the fulfilment of the related managerial, administrative and accounting obligations (legal basis: execution of a contract or pre-contractual measures);
- the possible protection of the rights of the Data Controller (legal basis: legitimate interest of the Data Controller).

The Data Controller may process, exclusively for the purposes indicated, only common data, such as, for example, personal data, telematic and telephone references, position/responsibility held within the client company/entity, together with economic and financial data, company name, registered offices, bank references of the client company/entity itself.

Your personal data will be processed in accordance with the principles of correctness, lawfulness and transparency for the management of the contractual and/or pre-contractual relationship and to follow up on your requests.

12.4 Mandatory nature of the provision of data and consequences of refusal

The provision of the Client's data is essential in relation to the proper performance of the contractual relationship with ECM, with the consequence that any refusal to provide them will make it impossible for ECM to carry out the same relationships.

12.5 Processing methods

The processing of personal data is carried out using manual, IT tools suitable to guarantee the security and confidentiality of the data and in any case in compliance with the appropriate security measures as required by **Regulation 2016/679 [art.32].**

The data may be communicated by ECM, within their respective and specific competence, to Bodies, Administrations, Associations and, in general, to any public and private subject, to internal subjects designated and in charge of data processing, as well as to those external subjects, responsible and/or appointed by ECM, to whom the communication is necessary for the execution of the services provided by ECM, including debt collection companies, which may be entrusted with the task of proceeding with the recovery of debts.

The dissemination of data is aimed exclusively at guaranteeing institutions and consumers about the issuance, existence, renunciation, suspension or revocation of certification.

12.6 Rights of the data subjects

The subjects to whom the personal data refer may exercise, at any time, the right to lodge a complaint with a supervisory authority and the rights provided for by **Regulation 2016/679**, by sending a specific written request through the channels

listed below. In particular, the subjects may legitimately request: a) the updating, rectification or, when interested, the integration of the data; b) the cancellation, transformation into anonymous form or blocking of data processed in violation of the law, including those whose retention is not necessary in relation to the purposes for which the data were collected or subsequently processed; certification that the operations referred to in letters a) and b) have been brought to the attention, also with regard to their content, of those to whom the data have been communicated, except in the case in which this fulfilment proves impossible or involves the use of means manifestly disproportionate to the protected right **[Regulation 2016/679 - Article 13 paragraph 2 points b) and c)].**

Requests can be addressed to ECM s.r.l. using one of the following channels:

- E-mail: info@entecerma.it
- Phone: +39 051 6705141
- Ordinary mail: ECM - Via Cà Bella 243/A loc. Castello di Serravalle 40053 Valsamoggia (BO)

12.7 Transfer of data to third countries or International Organizations

The Data Controller does not intend to transfer your personal data to a third country outside the European Union.

12.8 Data Retention Period

The data collected will be stored for a period of time not exceeding the achievement of the purposes for which they are processed ("principle of storage limitation", art.5, EU Reg. 679/2016) or according to the deadlines provided for by law. The obsolescence of the data stored in relation to the purposes for which they were collected is checked periodically.

12.9 Consent of data subjects

By signing these Regulations, the Client declares that he/she has read this information and consents to his/her personal data being processed for the purposes indicated above and also being communicated and disseminated within the scope of the purposes indicated.

13 REPORTS, COMPLAINTS AND APPEALS

13.1 Reports

This paragraph refers to communications concerning the activity and organization of CME.

Anonymous communications with generalized disparaging content are not taken into account.

Anonymous communications containing detailed information on the services provided and/or the behaviour of staff are handled as reports.

Reports can be received through:

- Written communication
- By e-mail
- by phone or verbally (with an explicit request to the whistleblower to send an email).

They must contain references and objective evidence that can lead back to the reliability of the content (e.g. copy of the documents that are the subject of the report).

All reports are handled as follows:

The Technical Secretariat receives all the reports, and takes care of the RT managers involved.

Reports are divided into the following types:

1. reports sent by competent bodies e.g. ON, Police, CIRCACB, Ministries, Accredia etc.:

2. reports sent by organizations, customers, or otherwise, veracity of certificates or otherwise;

Type 1 reports are analysed by the DG, the manager is appointed, RT, QA, etc.

Type 2 reports are analysed by ST and involve QA, and possibly RT, DG.

Both reports will be recorded by ST/AQ in a special "**Report Register**".

If the report relates to a request for information on documents attributable to CME, depending on the result of the verification and the type of documents, we can have the following flows.

Consequential action:

- Verification of negative veracity of documentation (forged and/or invalid documents);
- Reply to the requester for the information and any other information, if any;
- inclusion in the list on the ECM website, in the Certificate Verification section (bilingual: ita-eng) paragraph False and invalid certification - List button, from which a PDF file is opened containing the information relating to the certificates reported and verified as false. (http://entecerma.it/certificate.php);
- in support of what has been included in the list and in order to make the information more incisive, inclusion on the ECM website in the section WHO WE ARE / News/News & Events (bilingual: ita-eng). The box dedicated to "Online Verification Service" will always report the news relating to the last update of the above list (http://entecerma.it/news);
- Communication to the holder of the certificate for any warning;

The Management may apply further actions to guarantee its image and reputation.

If the applicants for information to CME are competent authorities (Accredia, Ministries, public administrations, etc.) the relative responses can be managed on the basis of the documents to be filled in that they will provide.

13.2 Complaint

The complaint can be submitted by any consumer as a natural or legal person, to report any anomaly pertaining to the safety of the product certified by ECM. Such a complaint must be substantiated and supported by supplementary materials (e.g. report). Complaints made anonymously, even if in writing, will not be taken into consideration.

- The "Customer **Complaints/Appeals Presentation" form** can be filled in by directly accessing the ECM website in the "**Customer Service > Information Request and Complaints-Appeals"** section.

ECM informs the natural or legal person who submitted the complaint in writing, within 30 working days, of the receipt.

The complaint will be evaluated by the Management, the sales representative, the DT, or the AQ, depending on the scope of the complaint. The Technical / QA Department examines the complaint in order to determine whether there are grounds to consider it unfounded or not.

For unfounded complaints, the Technical Management and/or the Sales Department contact the customer to inform him of the evaluation and settle the matter.

In the case of a well-founded complaint, a distinction is made between two cases:

1. if the complaint relates to CME's certification activities with objective reference to administrative, procedural and/or ethical inadequacy, the complaint will be taken over by the Technical Management or the General Management together with AQ.

The review will be conducted on the basis of the information provided and accepted by the customer and on ECM's internal procedures. The necessary corrective actions will then be implemented and appropriate preventive actions will be prepared, where necessary.

2. if the complaint relates to ECM activities with objective reference to the technical inadequacy of the product and/or documentation to the applicable legislative requirements, the complaint will be taken over by the Technical Management.

All complaints received will be recorded by ST/AQ in a special "**Reporting Register**" and the processing of the same will be carried out by the resolution committee together with the Legal Representative.

In the event that deficiencies and/or omissions are found to be unresolved by the review, the resolution committee will suspend the certification in the manner and within the time frame provided for in these regulations.

In the event that the product is found to be non-compliant due to defectiveness of the specimen due to errors in the production or installation process (if it is the manufacturer's responsibility), the resolution committee will carry out further investigations.

The Technical Management will send the customer a written communication containing, among other things, the request for the corrective/preventive actions that will have to be implemented and the time required for on-site verification of the same. At any time, the complainant may request the progress of the file from AQ.

The answer will be received within 30 working days. It should be noted that some information may not be communicated to the reporter as it is covered by professional secrecy and confidentiality of data towards the manufacturer.

13.3 Recourse

The Manufacturer/Authorised Representative requesting the certification, or the certification concessionaire, may appeal against the decisions of ECM by explaining and justifying the reasons for his disagreement within 30 days of receipt of the communication of the decision.

The appeal may be filed by the "Manufacturer/Authorised Representative" as a legal entity, to contest any error in the issuance, suspension or revocation of the certificate issued by ECM.

Such an appeal must be justified and supported by supplementary materials (e.g. report).

It means a Legal Entity, a natural person or a legal person that assumes the obligations and rights deriving from the exercise of the Organization and in possession of a VAT number. A legal entity is also a public legal entity (e.g. Region, Province, Municipality, Public Economic Bodies, Public Institutional Bodies such as the I. N.P.S., the I. N.A.I.L., universities, etc.).

Appeals must be submitted in writing by registered mail (registered letter with acknowledgement of receipt), fax, certified e-mail with a reply within 30 days of receipt of the document against which you wish to appeal.

The sender must specify the references of his/her organization, the subject matter of the appeal itself, the reasons, any attachments in support of the above reasons and the signature of the legal representative of the organization.

CME confirms that the appeal has been taken into account within 30 working days of its receipt, committing itself to provide information on the progress of the file, upon written request.

All appeals received will be recorded by ST/AQ in a special "**Reports Register**".

- The "Customer **Complaints/Appeals Presentation" form** can be filled in by directly accessing the ECM website in the "**Customer Service > Information Request and Complaints-Appeals"** section.

The ECM functions involved in the management of appeals, including for economic, administrative or procedural treatments, are managed by the Resolution Committee.

The acceptance or rejection of the appeal, duly motivated, will be communicated by the Legal Representative by registered mail or certified e-mail, within 60 days of receipt.

If the appeal relates to technical proceedings, the Technical Management assigns the review of the certification to a technician/team not involved in the conformity assessment activities subject to the appeal.

The findings are evaluated by the resolution committee.

The Legal Representative communicates the outcome of the resolution by registered mail or certified e-mail and therefore the acceptance or rejection of the appeal within 90 days.

13.4 Reserves

ECM informs its Clients that it is possible to submit reservations with respect to decisions taken by ECM.

Through its regulations, published on the Website (www.entecerma.it), ECM informs its clients that it is possible to present reservations during inspections or assessment of compliance and/or with respect to unethical/professional conduct of the auditors/inspectors who performed the inspection/audit.

The client may submit a reservation within 3 days from the date of communication by ECM.

The reservation must be sent to ECM in writing, by "Certified Electronic Mail, @mail, Fax, Registered Mail with return receipt".

Any decision taken regarding the CME reserve must be communicated within 30 working days, giving reasons.

In the event that the reservation is accepted, the treatments identified and the corrective actions necessary for its resolution must be recorded and archived by ECM.

14 JURISDICTION DISPUTES

Any dispute relating to the application or interpretation of the Certification Agreement referred to in these Regulations is an integral part, including those relating to its validity, execution and termination, will be referred to the exclusive jurisdiction of the Court of Bologna.

15 ACCEPTANCE CLAUSE

Upon acceptance of the offer, these regulations are also accepted by the "Manufacturer/Authorised Representative". Any revision will be sent by ECM to customers by certified mail and means of guarantee and will be accepted at the end of 5 working days from the date of sending.