REGULATION FOR PRODUCT CERTIFICATION
(REGULATION FOR PRODUCT CERTIFICATION)

ROLES ROLES	Name and surname (Name and surname)	Business Function (Business function)	Signature Date – DD/MM/YYYY (Signature date - DD/MM/YYYY)
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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 Certification Application form.

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

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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 of application of its trademark as indicated in chapter "4 - Concession of Use of Trademarks and Distinctive Signs" for the various homogeneous sectors of products admitted to certification. For products that can be certified within these sectors, the provisions of paragraph "2.1 - Certifiable products, Applicable procedures and standards".

The Directives for which CME is notified are indicated on the websites listed below.

These Regulations are available on the Body's website.

	WEBSITE	SEARCH
	Home CME (www.entecerma.it)	Official documents - Ente Certificazione Macchine (entecerma.it)
	ACCREDIA (www.accredia.it)	Databases > Accreditations > Accredited and Recognized Bodies
	European Commission	EUROPA – European Commission – Growth – Regulatory policy - SMCS

1.1.1 Revision history

The revision history of this document, which contains all the revisions carried out on it, with the date of issue and the reasons, can be found on a specially drawn up document which is (GDPR -HYDB)".
These regulations are available to interested parties on the CME website.

1.1.2 Applicability

These Regulations apply to the activities carried out by ECM, in relation to the EC 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 CME personnel involved.

1.1.4 Rights and Duties of ECM

1.1.4.1 ECM rights

- ECM reserves the right to use employees and/or freelancers to carry out conformity assessment activities.
- ECM reserves the right to refuse an application for certification if there is a risk of impartiality due to previous consultancy activities carried out for the same organization regarding the purpose of the certification itself.
- Furthermore, CME reserves the right to refuse an application for certification if it conflicts with the requirements or conditions of the organization of CME activities;
- ECM reserves the right to monitor for the period of validity of the certificate for modules that require Quality certification.

1.1.4.2 CME Duties

- Apply the requirements set out in this regulation to aspects specifically related to the scope of application of the certification itself;
- Keep all internal management system documentation up to date
- Prepare, provide and keep updated a detailed description of the certification activity, including the certification application, the assessment activities, as well as the process for issuing, maintaining, reducing, extending, suspending, revoking the certification and the renewal process, even in the case of risk of impartiality;
- If formally informed, notify the competent bodies and the accreditation body (see applicable directives/regulations) of cases in which certified companies are involved in processes related to the laws on defective product/service liability and safety;
- 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 possibly ACCREDIA (where relevant) of facts and situations that may compromise consumer safety following 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; ECM reserves the right to subsequently replace one or more team members in case of need or conflicts that have emerged after the agreements made;
- Guarantee the authenticity of the certificates. On the ECM website there is a section "**Customer Service >Certificate Search**" which 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 these 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 required, it may affix the identification number of the Notified Body Ente Certificazione Macchine S.r.l. (no. 1282) next to the CE mark required by the Directive in the manner provided for by the same;
- It can publicize the certification in the ways it deems most appropriate, as long as it complies with the rules defined in the chapter "4 - Concession of Use of Trademarks and Distinctive Signs";
- It 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, by giving written notice to ECM;
- You can request the Certificate on any type of support from ECM on condition that it bears 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 Scope of certification

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

The certification of a product is defined by European Directives, and or European Regulations and the criteria established by them, constitute a fundamental reference to which ECM strictly adheres. According to the provisions of "**Decision 768/2008 published in the Official Journal of the European Union on 13.8.2008**" from Annex II, Conformity Verification Procedures. This requirement is referred to in the forms linked to these Regulations, which the Customer comes into possession of once a request for certification has been activated at ECM, 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 for use by Clients to submit an official application for CE certification of a product towards 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 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 objectively and without 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 CoC Committee Member must be free from any commercial, economic, financial and other pressures that could influence their decisions.

The tasks assigned to the Certification Committee are mainly:

- Review of the evaluation activities of the certification process
- Decision on the granting of certification to the "Manufacturer/Authorised Representative"

1.3.2 CSI Committee for the Safeguarding of Impartiality

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 CDI Committee must be free from any commercial, economic, financial and other pressures that could influence their decisions.

The CDI provides an opinion on:

- The 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 affect impartiality and trust in certification, including transparency;

2 GENERAL CONDITIONS

2.1 Certifiable products, Applicable procedures and standards

2.1.1 Requested analysis (Data collection for offer 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 qualification categories 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 relevant conformity assessment, the products for which certification will be requested are established by the "Manufacturer/Authorised Representative" under his own responsibility with reference to the sector concerned, taking into account the following constraints:

- certification can be issued for prototypes, single specimens and/or for mass-produced products;
- The use of technical specifications instead of harmonised standards must 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 – Verification of products").

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

2.1.3 Certification guidelines

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 the application.

The technical file relating to the product to be certified must be delivered to the Body in Italian and/or English.

Following the analysis of the technical file, the Body will be able to evaluate whether to carry out tests and issue the relevant offer.

2.1.4 PRD Certification Process Workflow

The annex "Product Certification Workflow (GDPR -WF)" illustrates the general process of the certification process in relation 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 requesting 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 Authorised Party 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 with any reports from other NBs.

2.3 Delivery and collection of products

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

€ If, in exceptional cases, or when provided for by Directives, Regulations or Standards, ECM is required to directly take care of the sampling, transport or import of the products, the related expenses incurred by ECM will be invoiced with the surcharge 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 - ECM Officers") 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 tested must be collected by the "Manufacturer/Authorised Representative" concerned no later than 30 days from the communication 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 in advance of the return or disposal at public landfills of the aforementioned products, together with details of the estimated costs for the two options, which the "Manufacturer/Authorised Representative" will bear directly.

The prototypes and samples tested, if they are returned, are shipped in the condition in which they are after the tests. The "Manufacturer/Authorised Representative" is aware and accepts that the product may be damaged as a result of the performance 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 relating 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 concessions, if any, (so-called "rights");

2.6 Resources used by ECM for conformity assessment

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

(p.02) Verification activities at the manufacturer's premises and any of its authorised representatives are carried out by CME employees or external personnel, qualified according to specific procedures, in accordance with the applicable standards, and required to comply with the obligations of secrecy and impartiality.

On the occasion of the verification at the manufacturer, with regard 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 conformity 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 refuse the auditor and/or the operator 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 staff/auditors.

The Customer/Supplier will be informed of the activities subcontracted, may object within 5 working days from the date communication. For the management of suppliers and subcontracting and laboratories, reference is made to the procedure specification.

2.7.1 Prohibition of generating conflicts of interest and carrying out consultancy activities.

In carrying out the activities envisaged by these Regulations, ECM does not provide consultancy services in any way 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 the subjects engaged in activities related to the field for which certification is requested or already obtained.

2.8 Terms and definitions

In this document, the terms and definitions set out in the Directives, Regulations, and reference standards apply. Terms and definitions follow:

- '**manufacturer**' means any natural or legal person who manufactures machinery, apparatus or devices or who has it designed or manufactured, and markets it under his or her 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 to act on his behalf in relation to certain activities.
- the "**Manufacturer/Authorised Representative" who receive from ECM the concession use of the Certificate following a positive resolution by the ECM Certification Committee become the "concessionaire".**
- '**authorised representative**' means a natural or legal person established in the Union who has received a written mandate from a manufacturer authorising him 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 appliance originating in a third country;
- '**distributor**' means the 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;
- '**process**' means any activity involved in the manufacture of machinery, apparatus, devices or components thereof.
- '**audit team**' means a person, or group of persons, who carry out the audit activities in the company and take samples (where applicable) for the purpose of maintaining the EU certification. The number, skills and role of the members of the audit team are decided by CME, so as to ensure an analytical capacity suitable for the subject of the assessment.
- '**assessment activity**' means an activity carried out by ECM to assess the conformity of the product with the applicable reference requirements; it may be documentary, inspecting (factory) or testing.
- '**homogeneous batch of product**' is a homogeneous quantity from which statistically significant samples can be taken for the assessment of characteristics and compliance with the specified requirements.
- "**technical file**" means the set of documentation required by the various Annexes to the Directives and the mandatory Regulations that characterise 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 appliance;

- '**technical specification**' means a document prescribing the technical requirements to be met by the equipment;

- '**harmonised standard**' means the harmonised standard referred to in Article 2(1)(c) of Regulation (EU) No 1025/2012;
- '**accreditation**' means accreditation as defined in Article 2(10) of Regulation (EC) No 765/2008;
- '**national accreditation body**' as referred to in Article 2(11) of Regulation (EC) No 765/2008;
- '**conformity assessment**' means the process of demonstrating compliance with the essential requirements of this Directive relating to an appliance;
- '**conformity assessment body**' means a body that carries out conformity assessment activities, including calibrations, tests, certifications and inspections;
- '**recall**' means any measure to obtain the return of an appliance already 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;
- '**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 equipment complies with the applicable requirements laid down in the Union harmonisation legislation providing for its affixing of the equipment.
- "**non-conformity**" non-conformity" failure to meet a requirement established by the applicable regulatory, essential and safety 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 fulfilment;
ii. lack of or insufficient practical implementation of the aforementioned criteria and methods, initially (implementation of the requirement) and over time (maintenance of the requirement);
iii. both of the previous causes.

- '**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 do 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 respect of the overall effectiveness of the management system.

  or

  A finding that does not significantly influence 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 customer, approved by ECM, to resolve NCs and Observations;
- '**attestation of conformity**' means the formal expression of the results of a conformity assessment which has demonstrated that the specified requirements relating to a product, process, system or organism are met.
- "**complaint**" means an expression of dissatisfaction, both verbal and written, by entitled parties (direct customers, indirect customers, Public Authorities, Accreditation Bodies), with regard to the services provided by the Body and, in general, to its work.
- "**appeal**" means a formal appeal, by Parties with specific causes, against decisions taken or express assessments or certifications issued by the Body.
- "**litigation**" brought before legal proceedings by the Parties in title as above, to protect their rights and interests deemed harmed by the Body's actions.

3 CERTIFICATION PROCESS

3.1 REGULATORY AND LEGISLATIVE REFERENCES

The reference standards and directives for CME certification activities in the context of the application of these Regulations are the following:

	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 bodies carrying out inspections

◆	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 Accreditation Document for Notification Purposes
◆	CME requirements	Documentation of the Management System of Ente Certificazione Macchine S.R.L.
◆	Accreditation Schemes (Directives/Regulations) as defined in the annexes of the 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 in relation 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 taken care of by ECM (Resp. Commercial and/or Technical DIR) and its feasibility is verified in economic and regulatory terms. The request can be formalized by a descriptive sheet of the product to be certified as required for each directive or regulation. This form is the "Data Collection (QA07-17065_M01)" module.

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

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 mandatory legislation provides for an initial inspection of the manufacturer, if the assessment activity should reveal 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, surveillance will be carried out on the production process and/or on the management system.

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

Examples of justification:

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

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

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

3.2.2 Submission of the Offer - Contract

Any customer can make a request for a service offered by ECM for the conformity assessment of a product related to the Directives for which ECM has obtained authorization. The request can be formally sent in writing (e.g. by e-mail) or by means of an initial direct contact in verbal form (e.g. by telephone or videoconference).

If the request is made verbally, or if the written communication sent by the customer is not exhaustive, ECM will request additions. The request can also be made in writing through the "Data Collection (QA07-17065_M01)" form where the minimum information necessary to be able to assess the feasibility of the activity will be entered; or alternatively by sending the customer an email summarizing the request received verbally, containing the "Data Collection" form pre-filled by ECM, in order to clearly define the subject of the request for quotation.

- 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 times/costs established and available in the "**Tariff**" 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 Offer Acceptance Form – Contract.
- ECM carries out the review "**Quote, Offer, Contract (QA07-17065_M05)**" signed for acceptance by the customer, and agrees to take on the assignment for the certification process.

3.3 Establishment of the application

3.3.1 Opening of the Job Order

The UC in collaboration with UT provides:

- register the application, carrying out a preliminary review of the same 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 set out in the applicable Regulation/Directive;
- the submission, by the "Manufacturer/Authorised Representative", of test and/or evaluation reports from accredited Bodies/Laboratories recognised by ECM, by virtue of procedures and mutual recognition agreements, may allow ECM to omit the performance of certain activities envisaged 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 verified; these specimens 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 him. The procedure can also be carried out at the manufacturer's premises or in 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/Authorized Representative".

3.4 Certification process – Verification of products

3.4.1 Selection of samples for products to be certified

For each homogeneous range of products covered by the application for certification, 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 collection by ECM the representative specimens of the product belonging to the various production batches placed on the market during the year or during the previous verification by ECM.

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

The field verification of the samples is always preceded by the documentary analysis carried out by the staff 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 Verification management

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

Checks of the samples under test of various kinds are planned to be carried out at the ECM 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 on the sending of the samples to the ECM headquarters.

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

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

3.4.4 Non-conformance resolutions

The "Manufacturer/Authorised Representative" must undertake to eliminate any "non-conformities" detected during the aforementioned verification, 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, the timing of implementation of the corrective actions and related responsibilities, documentary evidence, etc.)

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

3.5 Issuance or issuance of certification

3.5.1 Issuance of the 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 – Verification of products") 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 assessment process is to be considered partial until the completion of the committee's resolution.

3.5.2 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, which specifies:

- the name and registered office of the certification concessionaire organisation,
- the production site(s) to which the certification relates,
- the product or the homogeneous range of products subject to certification,

- the standard or the technical specification of reference,
- conformity marks whose 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 amount agreed for the verification activity carried out.
- Expiration date (where applicable)

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 - Certification rejection").

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 evaluation 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 CNs have not been resolved, the CDC's opinion remains unfavourable to the issue of the certificate. The "Manufacturer/Authorised Representative" may no longer 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 as provided for in paragraph "13 - Reports, Complaints and Appeals".

In the event that the appeal still fails:

- ECM informs the competent authorities "Accredia, Ministries, CIRCACB" on the certification practices it restricts, refused, suspended, withdrawn.
- 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.

3.5.3 Certificate validity

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 lapses immediately.

In general, the validity of the certification is also subject to the evolution of technological progress for the modules to which it is applicable.

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 Forms A2, C1, C2: annual, renewable following the execution of the required production checks;
- Validity of the certification issued with the procedure referred to in forms D, D1, E, E1, H, H1: renewable three-year subject to the performance of annual surveillance checks;
- Validity of the certification issued with the procedure referred to in forms F and G: unlimited except for substantial changes to the certified copy.

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

Products 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 event of mandatory certification, they 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 places to verify the actual stock of the products in the warehouse on the date of expiry of the validity of the certificate.

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

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

Further reasons for the revocation 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 ECM, but also to the positive outcome of the surveillance activity where required in the form used.

- CME also has the permanent responsibility to ensure that the EC and EU-type examination certificate remains valid. ECM informs the manufacturer of any significant changes in the regulations or in the 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 have an influence on the validity of the certification, starting, if necessary, from a new process of evaluation, review and decision to the release of the official certification documentation / surveillance activities subject to 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 shall also inform the manufacturer of any finding and/or finding of incorrect transcription in the certificate of the date of issue, the index of the inspection, 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 email or other method valid for legal purposes. Decisions are also communicated to the competent bodies.

The Notes section of the reissued certificate will say "Cancel and replace certificate XXXX with incorrect transcription xxxxxxxxxx."

In the event of re-issue of the certification, the "Manufacturer/Authorised Representative" undertakes not to use the replaced certificate anymore and to return it to ECM.

3.5.4 Termination of the Contract with ECM

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

- For forms relating to a QMS, ECM will ask the Customer for a declaration of the products and their factory numbers made 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 Customer must inform ECM of the decision to terminate the contract by certified e-mail.

3.5.5 CME database or List of Issued Certificates

Following the issuance of the certificate, the data relating to the certification issued are entered in the CME 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 "Issued certificates", 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 for accessing the database have been provided.

ECM updates its list of certified customers with each new issue 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 reference regulations) is:

- Customer's business name;
- Certification validity status;

- Reference regulations and accreditation schemes;
- The site(s) covered by the certificate or the places of manufacture;
- Type of certified products including a clear identification of the certified product.

The above data can also be provided by ECM, upon request, to the 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 , it is possible to 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 website. In order to access the service, it is necessary to register.

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

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

3.5.6 Certificate renewal

Renewal of certification: to renew the validity of the certificate, if granted by the reference 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, according to the applicable modules according to the Directive or Regulation

Renewal audits must be carried out. For the renewal of certifications based on "type verifications" and/or laboratory tests, a new evaluation of the product will be required, 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 situation of the certificates issued, in any case notifies the holders of the certificates of the imminent expiry with notice.
- ECM, 15 days before the expiry of the certificate, will send 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 will be ordered;
  - 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 certified, as provided for in paragraph "3 - Certification Process".

In the event of non-renewal of the Certificate, it will not be necessary to notify the competent authorities.

3.5.7 Record-keeping

All documentation related to the certifications issued, including auditor records and those provided by the customer, are kept by ECM for a minimum of 10 years from the expiration date of the last certificate issued.

For the filing of the technical file (ATEX Directive), the storage of documents is 10 years from the date of filing.

Except in the Regulations and/or Directives, they do not indicate longer periods.

3.5.8 Manufacturer/Authorised Representative Obligations towards Samples and Prototypes

The "Manufacturer/Authorised Representative", in accordance with what is indicated in the offer/order, must keep and safeguard in an adequate manner and for the entire validity of the certification issued by ECM, providing for:

- keep the sample taken and identified by ECM, or the prototype tested in one's own 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 implies 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 waive the conservation of the specimen. To this end, it will be decided on a case-by-case basis how to proceed by formalizing it via email.

3.5.9 Procedure for the Filing of the Technical File (FT) ATEX Directive

For the ATEX Directive, with regard to some types of product, the procedure of simple filing of the FT in the ECM archives is envisaged. For this particular activity, ECM has only the task of keeping for a period of at least 10 years, with the possible extension requested by the customer for further years, to be sent with a written request to the commercial secretariat of ECM of the documents sent by the Customer (File).

The date on which ECM takes over the FT 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 product(s) to the ECM Sales Department.

ECM examines and assesses the FT's filing request.

To this end, if accepted, an offer is prepared for the FT 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 correctly closed in an envelope or envelope and identified must be sent together, or by certified electronic format (PEC) with an opening key for the authorities who request it to be viewed and to allow the verification of the legibility of said files to be sent to the customer. ECM.

- the verification of the applicability of the filing procedure is simultaneous with the signing of the review of the "**Application for certification (QA07-17065_M04)**" form;
- the evidence of 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 availability data.

3.6 CME Accreditation – Suspension, renunciation and revocation of accreditation

3.6.1 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 various schemes and sectors managed can be found out at any time, by consulting the links in paragraph 1.1 of the regulation.

3.6.2 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 to the organisation itself. ECM also notifies the competent authorities of any limitations, suspensions or withdrawal of the certificate.

3.6.3 Damage to non-accreditation

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

4 CONCESSION OF USE OF TRADEMARKS AND DISTINCTIVE SIGNS

4.1 Concession of use of trademarks

As of the date of issue of the certificate, the dealer has the right to use the marks granted by ECM, only with reference to the individual certification scheme or certification schemes for which he 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 govern 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 established in the legislation governing its affixing of the product; consequently the product can be sold throughout the European Economic Area (EEA).

4.2.1 Trademarks granted by ECM

The dealer can report on all copies of certified products the marks granted by ECM with the relative 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 subject to certification,
- during the validity period of the certificate,
- attributing the correct meaning to the certification of which the marks are attested,
- without changes in shape (enlargements / reductions are allowed to allow perfect readability),
- in any colors specified, i.e. in black and white;
- optionally, or where required by regulation, by placing the NB's number next to the CE marking;

If the EU Regulation provides, in accordance with Decision 768/2008, for a certification form for the assurance of product or production quality, total quality or other methods 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.

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4.2.2 ACCREDIA brand

This mark 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 its use)"** which is intended to be referred to here in full.

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.

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

4.3 Misuse of trademarks 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 not yet 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 models of products that have not been checked by ECM;
- the brands are combined with products not covered by certification;
- the marks are used in such a way as to be interpreted as marks of compliance with standards of the management systems of organizations;
- when the Applicant has not implemented the changes requested by CME.

4.3.1 Incorrect use of trademarks and certification – Actions taken by ECM

- As soon as the incorrect use of the certification, certificate or CE marking has been 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 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 shown on the product in accordance with the requirements of the standards or technical specifications used for certification, as well as the "special requirements" (see Directive or Appropriate Regulation on marking)

4.3.2.2 Copy of CE plate

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

4.3.2.3 Variation of identification marks

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

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 2.2.2 of this Regulation.

(p.02) keep under control the activities and processes that influence 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 with systematic tests – directly, or using third-party laboratories – the certified production, in order to ensure 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 subject to the consent of ECM; in the same way in the case of use of external laboratories, always subject to 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 change 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 type reference or model number

(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, date and production batch, applying the references suitable for tracing the origin of manufacture, through 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 and non-certified products, on its catalogues or price lists and on propaganda in general, not to make any declaration or advertise its certification in such a way that it can be considered misleading or unauthorized;

(p.09) not to use your certification in a way 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 the 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 the related management

(p.12) allow all CME staff in charge of access to the production sites, including the staff of the competent and/or Notification Authority, accompanied by the staff appointed by CME; these situations, which are aimed at evaluating the work of the personnel 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 evaluators 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) to 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 related 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) Store and make available to ECM, the representative specimens of the product belonging to different production batches placed on the market during the year or during the previous verification by ECM;

(p.17) If the customer carries out trials/tests at its plants, the customer must ensure that the test/test areas are "adequately suitable for the execution of the tests", and must also ensure that "its own staff, in charge of the tests" is suitable to carry out the activities;

(p.18) Communicate to the NB the changes it intends to implement on its QMS and wait for explicit authorization from CME before implementing them (only for management system certification procedures)

5.2 Certification change

If the dealer intends to change the scope of the certification, he must make a written request to ECM, which will decide whether or not a new test or verification activity is necessary. The costs related to this request are borne by the concessionaire 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, conferral of a particular branch of the certification concessionaire organization.

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 of suspension or revocation of the certification.

In the cases described, the organization must submit to ECM a written request for the maintenance of the certification by the subject 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 full 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 Safety at work – obligation to provide information

In accordance with the 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 CLASSIFICATION AND MANAGEMENT OF FINDINGS UPON VERIFICATION

6.1 Product non-conformity

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

The Non-Conformity may give rise to the adoption of one of the measures suspending the certification process, revocation of the 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, user safety, product safety and/or the integrity of the Quality System;

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

In the event of non-compliance, whether in the initial certification or renewal phase, the manufacturer must provide evidence of taking charge and must provide for the resolution within the pre-established times indicated at the time of transmission of the non-conformity by ECM. In the event that the deadlines are not respected, the certification or renewal process is blocked.

6.2 Product comments

The survey formalized as an 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 fulfilled it is reclassified as Non-conformity. It is determined by minor deficiencies that do not affect the manufacturer's ability to ensure the conformity of the Product with the conformity requirements for obtaining and/or maintaining certification.

6.3 Product Comment

The remark 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 Survey management

ECM 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 deadline for the resolution of the findings is 60 days. After 60 days, the suspension is carried out and reported to the Notifying 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 certification, at any time during ITER, by written request. The renunciation can be linked to internal problems of the manufacturer.
In the event that the Manufacturer renounces the certification with a written request, he 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.
The deposit paid or any total amount, in this case, will not be returned 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 the event of renunciation, the manufacturer is required to stop using the certificate issued by ECM and to suspend the marketing of products marked under this certification from the date agreed with ECM.

The waiver will be communicated by ECM to the Authorities in charge.

a) in the event of withdrawal;

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

c) when it does not accept the changes made to these Regulations and/or to the related special requirements for products subsequent to the entry into force of the new Regulation (see "8.2 - Amendments to this Regulation");

d) when it does not accept the changes in the tariffs relating to the annual rights to maintain the certification (see "9.2 - Change in the CME Tariff");

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

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

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 mark related to the certification on the products concerned and not to increase the related 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 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 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 that may affect the conformity of the product with the relevant Directive, subject to a decision of the Certification Committee.

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

In this case, the organization loses the right to refer to said certification.

Certification may be suspended when CME has reason to believe that the certified product no longer meets the legal, legislative and/or regulatory requirements and, in particular, in the following cases:

- non-compliance, by the "Manufacturer/Authorised Representative", of the obligations provided for in art. 5 above;
- detection of serious or large number of non-conformities; failure to take corrective action and, in general, negative outcome of surveillance checks.
- impossibility to carry out surveillance visits according to the indicated time intervals
- at the Organization's justified request (such as company crises, suspensions of 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 is submitted to the deliberation committee.
- In the event of suspension of the production of the certified product, the Organization may request the suspension of up to a maximum of 6 months, except for those modules where the expiration date of the certificate is less than 6 months on the date of suspension, in this case the expiration date of the certificate will be taken as the expiration date.
- 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 ECM, for any reason,
- serious non-compliance with these regulations;
- production of the product with deficiencies in compliance with the essential requirements of the relevant Directive;
- production 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 notify changes to the product/process or management system;
- failure to communicate judicial measures, or serious irregularities related to the certified system;
- failure to communicate the change of company name or relocation of the production site;
- refusal of the manufacturer to provide the sample(s) necessary for the repetition of tests and conformity checks;
- denial by the manufacturer of access to 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 adapt within the time frame provided for by the new legislation;
- repeated non-payment of certification fees, in whole or in part.

The suspension of the certification can 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 time limits for any corrective actions.

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

All the recordings and evidence collected will be submitted to the certification committee which will decide on the withdrawal of the suspension, the continuation of the same or the revocation of the certification.

€ The costs incurred by ECM 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 suspending certification

7.4.1 During the period of suspension of certification, the manufacturer

- 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 the marks referred to in Chapter "4 - Concession of Use of Trademarks and Distinctive Signs", nor qualify as a Certification Concessionaire Organization;
- in any case, he is required to pay the amounts for maintaining the supervision of the certification.
- segregate and identify as non-compliant any products already in stock and withdraw those that may have already been placed on the market, if the suspension derives from technical problems;
- Do not use the notification number in conjunction with the product with the 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 in the warehouse checked by ECM, for these products, equivalent extraordinary procedures for the control must be agreed.

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

- treatment: it must be implemented in the shortest possible time;
- communication of the proposed corrective action no later than 15 working days from the communication 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.

CME in turn:

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

The suspension can be cancelled only if the concessionaire has remedied the remarks made, adopting the appropriate corrective actions and also demonstrating that it has adopted those preventive actions aimed at avoiding the

repetition of the non-compliance within the established times and terms.

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

Before proceeding with the restoration 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 are borne by the manufacturer.

7.4.2 Suspension Measures

Suspension measures have a maximum duration of 6 months, except for those forms where the expiry of the certificate is less than 6 months. After this period, in the absence of restoration of compliance, the certification is revoked. A period of 6 months is provided as it is considered a reasonable period to allow the manufacturer to order the adoption of appropriate Corrective Actions in the event of Non-Conformity.

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 by 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 deferrals of payments, which must be authorised by the Management of ECM.

If the "Manufacturer/Authorised Representative" persists in his failure to pay the sums due, after a further 30 days of delay and suspension, the certification is automatically revoked by the ECM Presidency.

The measure of suspension of the certification and any measure of restoration are communicated to the "Manufacturer/Agent" by certified email or other method valid for the purposes of the law.

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, of the notification number such as to bring ECM into disrepute
- The certification can 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 for 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 "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 the mark;

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

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

f) failure to cancel the suspension of the certification, as provided for in paragraph "7.4 - Consequences of suspending certification".

The revocation of certification for technical reasons is decided by the certification committee that approved it and is 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 Notifying 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 – Verification of products").

7.6 Consequence of the revocation of the 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 trademark or trademarks granted for use;
- not to use copies and/or reproductions of the withdrawn certificate;
- not to advertise and use the revoked CE/EU Certifications, removing the logo and references to ECM from the documentation in use;
- cease to affix the CE marking on products referable to the revoked EC/EU Certification and, consequently, cease marketing
- eliminate from all products (including those in stock), from catalogues and from all documents known as trademarks, as well as any reference to the certification itself;
- provide for the payment of all amounts due to ECM.

ECM in turn provides:

(a) to interrupt the monitoring activity referred to in paragraph "6 - Certification Surveillance";

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

c) communicate the revocation measure to the competent authorities concerned.

7.7 Certification rejection

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

After examination and confirmation, the certification committee will activate a process for managing the refusal of certification; The measure will be made known to the applicant, motivated and documented.

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

7.8 Consequence of the refusal to issue the certification

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

- not submit to another Notified Body the request for certification for the same product;
- if it is still desired to proceed with the certification of the same product, to evaluate the correction of the project / product / system according to the NCs found and to propose and agree with the NB on the most suitable system to resolve the NCs on the product or system of the organization

7.9 Special requirements

7.9.1 A request from an organization to transfer its certificate from another ON to CME 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 apply, defined in compliance with the IAF-MD2 Guide.

If the crediting of the transferring CB 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 if it occurs earlier) and must last at least 1 day in the case of suspension and at least 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 eligibility of the certification being transferred and to carry out a pre-transfer review, the Machinery Certification Body must verify and have:

- confirmation that the customer's certification falls within the accredited scope of the issuing and accepting certification body;

- confirmation that the accredited scope of the release certificate falls within the scope of the MLA (Multilateral Agreement) of its accreditation body.

In addition, the applicant must provide:

- the reasons for the request,
- sending the original certificate of the Organization;
- the first certification report or 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;
- considerations relevant to establishing an audit plan and audit programme;
- any current commitment by the transferring client with regulatory bodies relevant to certification in relation to legal compliance.

ECM will not issue certification to the transferring customer until:

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

Where the pre-transfer review (document 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 problems, ECM assesses whether it is necessary to perform a pre-transfer visit in the field before the certification is issued or if the documentary evidence sent by the Organization is sufficient to issue the certificate, a decision that will be communicated to the Customer.

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

The certificate issued must show the date of first issuance (by the issuing 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 the periodicity of surveillance of the original certificate.

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

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

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

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

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

8.1 Amendment or repeal of the relevant standards or technical specifications

Should the Directive, the standard and/or the technical specifications of reference be amended 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 the decisions taken by CME or to reject them; in the latter case, the certification is revoked, in the manner described above.

In the event 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 requirements of the regulations.

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

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

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

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 provide for the acceptance by the "Manufacturer/Authorised Representative" requesting or concessionaire of the certification, 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 reply by e-mail or certified e-mail within 5 working days of receipt of the communication of the change in the Regulation, the relevant changes will be considered tacitly accepted.

9 RATES

9.1 Amounts and maintenance fees and monitoring of certification

The amounts relating to certification activities and maintenance rights, 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 CME 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 a review of the order in the event that there are changes with respect to what was received with the request.

Variations can result from:

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

9.2 Change in the CME Tariff

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

What is established in 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 rights to maintain the certification will be communicated to all the certification concessionaire organizations or those 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 withdraw from the certification within one month from the date of receipt of the communication relating to such changes; In the absence of waiver, the variations are considered accepted.

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

9.3 Terms of payment

As a general indication, each offer provides for the payment of a deposit specified in the offer, at the time of submission of the certification application, 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 reliability data of the applicant.

If the directive or certification scheme provides for periodic surveillance, an offer will be prepared containing the times and deadlines for carrying out the inspections as well as the related remuneration.

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

10 LIMITS OF CERTIFICATION AND LIABILITY

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

(p.01) The issue and maintenance of the product certification do not constitute a guarantee by ECM of compliance with the 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 itself and towards third parties, for the correct performance of its processes and the compliance of its products with the relevant requirements of a mandatory nature, 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 ECM and its employees, auxiliaries and collaborators harmless from any complaint, 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 liability 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 Breach – 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 evaluation activity carried out at the time of the error and/or omission that caused the damage.

10.3 Forfeiture clause

Any claim 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 claim.

11 DURATION OF THE CERTIFICATION CONTRACT

11.1 Contract

The Contract (see "3.2.2 - Submission of the Offer - Contract), of which these Regulations constitute 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 formulated 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 the validity of the certificates, as prescribed by the applicable Directives/Regulations.

11.2 Contract Termination

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

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

11.3 Validity of the contract

In the event of withdrawal of 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 reference technical specifications remain valid for the remaining time 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 ceased. 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 of personal data 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 towards the ACCREDIA Accreditation Body. Access to and consultation of certification documents 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" is required to be communicated or disclosed due to legal obligations, ECM will notify the applicant in writing, for example if a consumer files 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 occur (art. 326 Criminal Code) This clause is deemed not to apply, 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 Customer 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 the contractual relationship with the Customer, both on a legal level (e.g. fulfilment of accounting, tax, etc.) obligations. etc.) and on a commercial level (e.g. for sending your catalogues, brochures, etc.).

The data related 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 only handled 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 envisaged "**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 to:

- 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, renunciation, suspension or revocation of the certification ("7 - Waiver, Suspension, Revocation of Certification").
- the performance 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, office/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, 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 Customer's data is essential in relation to the correct performance of the contractual relations 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 for guaranteeing 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, as far as their respective and specific competence is concerned, to Bodies, Administrations, Associations and, in general, to any public and private entity, to internal subjects designated and in charge of data processing, as well as to those external subjects, managers and/or persons appointed by ECM, to whom communication is necessary for the execution of the services provided by ECM, including credit recovery 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 issue, existence, renunciation, suspension or revocation of the 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, correction or, when there is an interest, 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 as regards 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 - art.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 verification of the obsolescence of the data stored in relation to the purposes for which they were collected is carried out periodically.

12.9 Consent of the data subjects

By signing these Regulations, the Customer declares to have read this information and consents that their personal data will be processed for the purposes indicated above and will also be 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 on the behaviour of staff are handled as reports.

Reports can be received through:

- written communication
- by email
- by telephone 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. copies of the documents subject to the report).

All reports are handled as follows:

The Technical Secretariat receives all reports, and is interested in 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 other, certificate veracity or otherwise;

Type 1 reports are analysed by the DG, which instructs the operator, RT, QA, etc.

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

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

Consequent action:

- Verify that the document has been issued or not by ECM;
- Verify any counterfeiting on documents issued by ECM;
- Reply to the requester of the information and any other information, if applicable;
- Inclusion in the list on the ECM website, in the Customer Service section dedicated to false documents and improper use of the notification number 1282 (bilingual ita/eng), paragraph Invalid and/or counterfeit certificates/other documents, clicking on the button opens a PDF file containing information relating to the certificates subject to the reports and verified as false/counterfeit. (https://www.entecerma.it/servizio-clienti/certificati-falsi-e-uso-improprio-del-nr-1282/);
- 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 News section (bilingual ita/eng), of the communication relating to the updating of the list of invalid and/or counterfeit documents. The communication will include the link to the latest update of the aforementioned list. (https://www.entecerma.it/aggiornata-la-lista-dei-certificati-non-validi-e-o-contraffatti/);
- 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 CME information are competent authorities (Accredia, Ministries, public administrations, etc.) the relative answers can be managed on the basis of the documents to be filled in that they will provide.

13.2 Complaint

The complaint can be made by any consumer in his or her capacity as a natural or legal person. Such a complaint must be substantiated and supported by supplementary materials (e.g. report). Complaints made anonymously, even if written, are not taken into consideration.

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

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

The complaint will be evaluated by the Management, the sales representative, the DT, or the QA, depending on the scope of the complaint. The Technical Department/QA examines the complaint in order to determine whether there are grounds for considering it unfounded or not. The assessment of the complaint is entrusted to persons not involved in the management of the activity that is the subject of the complaint itself.

For unfounded complaints, the Technical Department 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, two cases are distinguished:

1. if the complaint relates to CME certification activities with objective reference to administrative, procedural and/or ethical inadequacy, the complaint will be taken care of by the Technical Department or the General Management together with QA.

The review will be conducted on the basis of the information provided and accepted by the client 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 care of by the Technical Department.

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

In the event that there are deficiencies and/or omissions that have not been resolved by the review, the resolution committee will suspend the certification in the manner and within the time limits 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 task), the deliberation committee will carry out further checks.

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

The response will be 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 concessionaire of the certification, may appeal against the decisions of the CME by explaining and justifying the reasons for his dissent within 30 days of receipt of the communication of the decision.

The appeal can 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).

Means Legal Entity, natural person or legal person who assumes the obligations and rights deriving from the exercise of the Organization and in possession of the 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 post (registered mail with return receipt), fax, certified e-mail with a response within 30 days of receipt of the document against which you wish to appeal.

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

ECM confirms that the appeal has been taken care of within 30 working days of its receipt, undertaking to provide information on the progress of the file, upon written request.

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

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

The CME 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 Electronic Mail, within 60 days of receipt.

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

The results 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 customers that it is possible to have reservations with respect to decisions made by ECM.

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

The customer 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".

For any decision taken relating to the CME reserve, it must communicate within 30 working days, justifying them.

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 LITIGATION

Any dispute relating to the application or interpretation of the Certification Agreement referred to in these Regulations constitutes 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

At the time of 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.