

	MACHINERY CERTIFICATION BODY	Document Code (Document code)	RGVOL01	Revision number (Version number)	Rev. 05	Status: Draft / Approved (Draft / Approved)
		Effectiveness date	14/03/2025	Expiration Date (Expiry date)	----	APPROVED

REGULATIONS FOR NON-NOTIFIED VOLUNTARY CERTIFICATION (ISSUANCE PROCEDURE AND INSTRUCTIONS)
REGULATION FOR VOLUNTARY CERTIFICATION NOT NOTIFIED (ISSUANCE PROCEDURE AND INSTRUCTIONS)

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1 PURPOSE AND SCOPE

1.1 Generality

These Regulations, approved by the Top Management of Ente Certificazione Macchine S.r.l. (hereinafter ECM), establish the "Non-Notified Procedure" hereinafter referred to as "Voluntary Certification", and which is applied by ECM for the voluntary certification of products and production processes. This procedure provides information and instructions on:

- the meaning of this voluntary certification;
- the terms and conditions for manufacturers to ask ECM to issue voluntary certification ;
- the CME process to issue this voluntary certification;
- How to use this voluntary certification.

Important notes:

- The CME company specifies that this is a "NOT NOTIFIED" activity;
- The manufacturer under his sole responsibility may CE mark his products only if he deems it appropriate. ECM will have no responsibility for this step.

ECM undertakes to carry out only and exclusively voluntary certificate issuance activities in compliance with the note of the "European Commission of 14 September 2022 Ref. Ares (2022) 6342894" and the communication received from the "Ministry of Economic Development Directorate General for the Market, Competition, Consumer Protection" and the "Technical Regulations Div. VII – Notified Bodies and Accreditation Systems Notifying Authority - NANDO Contact Point for Italy".

The procedure of "Issuance of the Voluntary Certificate" is applied and carried out by a "Department of the CME Company" which DOES NOT INVOLVE the staff of the Notified Body; this procedure is applied using employees, or freelancers (excluding those used by the Notified Body for mandatory certification tasks).

The use of "Voluntary Certification or Voluntary Attestation" is closely linked to the terms set out in these Regulations. You may not use the "Voluntary Certification" until you have carefully read these regulations.

These Regulations can be downloaded from the Website WEB – Ente Certificazione Macchine S.r.l.

	WEBSITE	SEARCH
	Home CME (www.entecerma.it)	ENTE CERTIFICAZIONE MACCHINE SRL Customer Service > Official Documents > Regulations

2 APPLICABILITY

These Regulations apply exclusively to the activities carried out by CME, in relation to the "Non-Notified Voluntary Certification Procedure". This "Voluntary Certification" can be issued by ECM to all types of customers located in the "European Economic Area or outside Europe" without any discrimination, subject to exclusions imposed by competent authorities.

For the issue of the "Voluntary Certification", CME carries out its own assessment of the documentation provided by the customer, at its sole discretion. Furthermore, this activity does not fall under consultancy.

3 DEFINITIONS

Definition	Full definition
VOLUNTARY CERTIFICATION	It is the official expression of the results of the evaluation of the documentation submitted, aimed at demonstrating compliance with the requirements of specifically identified standards/regulations [hereinafter referred to as "CC"].

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	It is issued on a voluntary basis, essentially on the basis of the request of the Customer, who operates in the interest of an end user;
CERTIFICATION HOLDER	organization that has requested and obtained the issuance of voluntary certification by ECM.
COMPLAINT	form of dissatisfaction, both verbal and written, with the services provided by ECM.
APPEAL (OR APPEAL)	formal act, on behalf of the subject, having specific causes, against the decisions taken or the assessment expressed by ECM.

4 WHAT IS VOLUNTARY CME CERTIFICATION

- (p.01) The ECM Company undertakes to carry out only and exclusively voluntary certificate issuance activities in compliance with the note of the European Commission of 14 September 2022 ref. Ares (2022) 6342894 and the communication received from the Ministry of Economic Development Directorate General for the Market, Competition, Consumer Protection and Innovation .Technical Regulations Div. VII – Notified Bodies and Accreditation Systems Notifying Authority - NANDO Contact Point for Italy.
- (p.02) The Client undertakes to provide ECM with appropriate technical documentation to be analysed, subject to verification of standards and/or directives and/or regulations [hereinafter referred to as "Technical Documentation"], in order to enable the Company to perform its services correctly and in any case in the best possible way.
- (p.03) The ECM activity will consist of a verification of the Technical Documentation made available by the Client and immediately returned as it contains sensitive data at the end of the activity carried out, where in the event of a positive outcome of the verification the Company will issue a voluntary "CC" certification, always in compliance with the note of the European Commission of 14 September 2022 Ref. Ares (2022) 6342894.

With regard to the CC between the Parties, it is expressly agreed that:

(p.03.01) The CC is the output of the requirements assessment carried out by EMC Company and is issued on a voluntary basis, essentially on the basis of the request of the Customer, who operates in the interest of an end user;

(p.03.02) The CC does not represent a certification process, but only a documentary verification carried out on a voluntary basis of the technical documentation **receipt**.

(p.03.03) The CC cannot be used to export and/or place products within the European Community as it is not an EC Certificate of Conformity nor does it replace the EC declaration of conformity, the latter attestations that the Company does not offer, with the consequence that the manufacturer holding the CC issued by the Company, remains the sole responsible for any obtaining of regular CE certification, not being in any way exempt from carrying out all the activities necessary to place its product on this market, if necessary by contacting a Notified Body.

(p.03.04) The form "Acceptance of the Voluntary Certification Regulations (QAT10_M02)" must be completed and signed by the "Client" and returned together with the other documents necessary to carry out an assessment by ECM.

These assessments are voluntary and are not performed by CME as a Notified Body, but as an independent party. Furthermore, this activity does not fall under consultancy.

For these reasons, the output of this verification of the documentation is a reliable opinion of ECM as an independent party, which is reported by ECM itself in writing within a document called "Voluntary Certificate" that ECM issues.

5 PURPOSE OF CERTIFICATION/VOLUNTARY CERTIFICATE

The purpose of voluntary Certification is to demonstrate (with the level of confidence associated with an independent party verification) that it meets the standards or specifications of CME. This is achieved by means of an assessment of the technical documentation, carried out before the voluntary certification is issued.

6 CONDITIONS FOR THE USE OF THE CERTIFICATION/VOLUNTARY CERTIFICATE

Voluntary certification:

- It has NO legal value, unless it is used between private companies with specific agreements between them;

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- It is NOT required by law (it is voluntary) and is intended for use between the manufacturer and the manufacturer's customer;
- The documents issued by ECM may not be reproduced, in whole or in part, in such a way as to induce the consumer to consider the final product compliant with any applicable mandatory legislation. Documents issued by ECM may only be mentioned in the same words as those used by ECM and in full form, including the date of issue;
- It is NOT an authorization of ECM to apply CE certification on a product;
- It does NOT originate from customs requirements or to demonstrate to the authorities the compliance of products with the requirements for CE marking;
- It can NOT be used to demonstrate the conformity of the product to the Authorities;
- It may NOT be used during government inspections;
- It can only be used for purposes authorized by law.

Please note that some Directives/Regulations require the use of Notified Bodies: the "Voluntary Certificate" is NOT associated with any activity of Notified Bodies nor is it mandatory to meet legal requirements.

On the contrary, it declares ECM's opinion that the manufacturer, under its own responsibility, can apply the CE Certification on the product if it complies with the applicable directives under its own and total responsibility.

Voluntary certificates are NOT issued by CME as a Notified Body.

The "Certificate issued by CME as a Notified Body" is associated with a completely different purpose from that of the "Voluntary Certificate".

The "Voluntary Certificate" has nothing to do with the certificates issued by CME as a Notified Body. Don't confuse these two types of certificates: if you are unsure, contact ECM.

The holder of the "Voluntary Certificate" may NOT use the "Voluntary Certificate" outside of the purposes listed above without official authorization from CME to do so.

If you have any doubts about the use of the "Voluntary Certificate", do not use them and contact ECM: info@entecerma.it

7 FEATURES AND DESIGN OF VOLUNTARY CERTIFICATION

The most commonly used format of the "Voluntary Certification" is a "Rectangle with Rounded Edges", with the "CME Circle" inside. It is shown in "Figure 1" below. The color used for all shapes is blue, the scales are gray, and the background is white.

The "Voluntary Certification" may not be modified in form, color or content. Its size can be changed, but maintaining the same aspect ratio as in the example in "Figure 1".

In particular, the dimensions of the "Voluntary Certification" logo, if shown next to the "CE Certification" or the Logo of the Holder of the Voluntary Certification" must not be larger than these two.

ECM can issue different types of certificates in the voluntary field, corresponding to the different templates included in the list of certificates and marks (Master List/Voluntary Certificate Templates and "QAT10_Master" Markings).



Figure 1

8 CRITERIA FOR REQUESTING THE ISSUE OF VOLUNTARY CERTIFICATION FROM ECM AND THE PROCESS FOR OBTAINING IT

Voluntary certificates are issued by CME on request and on a voluntary basis.

They are issued with reference to a documentary analysis and after verification by an ECM employee; they are issued only if, in the opinion of an ECM technical expert, the documentation complies with the requirements that ECM has established internally.

The process of issuing the voluntary Certification by ECM consists of the following phases:

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1. Request by the Client for the feasibility of issuing a voluntary certificate;
2. Acceptance of CME and preparation of the economic offer where required;
3. Acceptance of the offer by the customer and shipment of the order to ECM where required;
4. Verification of documentation by a CME technician;
5. Once the documentation has been verified by a Technical Expert, and a positive evaluation has been obtained, a draft of the voluntary certificate will be prepared and sent for approval to the Services Department.
6. The person designated within the organization as CME Services Directorate will sign and issue the voluntary certificate as responsible for approving and issuing the voluntary certification.

9 RESPONSIBILITIES AND RIGHTS

9.1 Specific obligations of the Customer

9.1.1 Holder of the Voluntary Certification

The holder of the Voluntary Certification is solely responsible for its use.

The purchaser as the dealer of the voluntary certificate remains solely responsible for its use and dissemination throughout the market. Any violation or incorrect use of the same will be attributable only to the concessionaire.

9.1.2 Use of Certification

The certification holder must use the Certification according to the rules set out in chapter "Conditions for the use of the certification/voluntary certificate" of these Regulations;

- in general, he must behave and act in accordance with the rules set out in these Regulations;
- must provide ECM with all the technical documentation, in Italian or English, necessary to start the process of issuing the voluntary Certification according to the instructions in the chapter "Criteria for requesting the issue of voluntary certification from ECM and the process for obtaining it". of this Regulation;
- may not allow others to use the Voluntary Certification on behalf of the owner;
- may not associate any slogan of the holder of the Certificate to the voluntary Certification;
- may not combine the Voluntary Certificate with any other logo or certification that may change its meaning or be misunderstood by the end user of the Certificate;
- can never associate voluntary certification with mandatory certification, which can only be used by accredited organizations and an accreditation body;
- must ensure that all possible end-users of commercial, advertising and promotional material referencing the Voluntary Certification do not misunderstand the scope of the Voluntary Certificate itself, thinking that it is applicable to products or activities outside the actual scope of the Voluntary Certification;
- may not use the Voluntary Certificate in a manner that damages the reputation of CME and undermines the trust of all possible interested parties;
- must be available for any additional verification requests from ECM.

The Voluntary Certificate Holder may (rights):

- use the Voluntary Certificate under the conditions and according to the rules mentioned herein. This right is no longer valid after the expiration date of the certificate;
- use the Voluntary Certificate for internal use (within the company of the Voluntary Certification Holder) or externally for voluntary demonstration purposes.

9.2 ECM's responsibilities and rights

9.2.1 Confidential Information and Intellectual Property

The Parties are aware that during the execution of this agreement they may come into possession of professional secrets and/or confidential commercial information, for which it is specifically understood:

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- **Professional Secrecy:** means any information, including, but not limited to, technical or non-technical data, a formula, model, program, plan, device, method, technique, design, process, financial data, financial plans, product plans, or a list of actual or potential customers or suppliers;
- **Confidential Business Information:** means any non-public information of a sensitive or personal competitive nature, other than trade secrets, acquired by the Client in connection with the performance of services for the Company, including (without limitation) oral and written information regarding the Company's financial positions and results of operations (revenues, margins, assets, net income, etc.), annual and long-term business plans, marketing plans and methods, accounting invoices, oral or written customer information, and personnel information.

9.2.2 Commitment to Confidentiality

(p.01) The Parties undertake to maintain the strictest confidentiality and not to use or disclose, except in accordance with any written instructions, any Professional Secret or Confidential Commercial Information obtained in connection with the execution of this agreement, as long as the relevant data and/or information can be considered secret or confidential.

(p.02) The Client, in particular, shall maintain the utmost confidentiality and undertake, except as necessary to carry out his duties, not to use or disclose any commercial information expressly qualified as confidential, or reasonably to be considered as such according to the canon of good faith commensurate with expert operators in the sector, inherent in the Company during the term of this agreement and for a period of five (5) years following the expiry of the voluntary certification.

(p.03) The Parties may disclose Professional Secrets or Confidential Commercial Information of which they are aware only in response to a request from the Judicial Authority or other Public Bodies, at the end of a legal proceeding requiring the disclosing party to do so, provided that the request to disclose the Professional Secrets or Confidential Commercial Information in this way gives time to allow the Company and/or the Client to seek an appropriate arrangement protection.

(p.04) In the event that the Client violates or threatens to violate the provisions of this chapter, the Company shall be entitled to fair compensation taking into account all damages directly and indirectly incurred as a result of the disclosure and/or use of confidential information under this Agreement.

(p.05) The commitments referred to in this paragraph 03 are made by the Parties for themselves and for their employees, who must guarantee the utmost confidentiality of all information acquired during their activities, safeguarding all the property rights of the Parties.

9.3 ECM Responsibilities

(p.01) In no way can ECM be held responsible for any defects and/or non-conformities on the product and/or inaccuracies on the documentation used by the Holder of the voluntary certificate.

(p.02) The CC and in general the activity carried out by the Company, will be bound by the request made by the Customer, the information provided by the same and the Technical Documentation, in no way will the Company be able to receive disputes about the object of the verification and in-depth analysis carried out.

(p.03) Initiate an investigation of any complaint or notice from the market, as deemed appropriate, in accordance with the instructions in the "Complaints, Appeals (APPEALS) and protests" of these Regulations and, if deemed necessary, withdraw the voluntary certificate;

(p.04) In the event that ECM detects in the market or is informed of the presence of a false Certification, it publishes the document on its website (section "false certificates") and decides whether or not to report it to the judicial authorities.

ECM is NOT responsible for any "CE Certification" of the product indicated on the voluntary certificate.

9.4 Express termination clause

These regulations shall be considered terminated by law pursuant to "art. 1456 of the Italian Civil Code", in the event of a written communication by which the Company expresses its intention to avail itself of this clause, in the following cases:

- violation by the Customer of the payment terms referred to in the payment chapter;
- breach by the Client of the confidentiality obligations referred to in chapter "Responsibilities and rights About ECM";
- violation by the Customer of one or more provisions of these regulations;

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9.5 Payment clause

The Management of ECM may also order the suspension of the voluntary 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.

10 ARCHIVING OF TECHNICAL DOCUMENTATION

ECM is NOT responsible for archiving the Manufacturer's technical documentation.

In general, the Manufacturer's documentation is NOT archived either in paper form or in its CME database after the voluntary Certificate/Certification has been issued.

It is the responsibility of the Manufacturer to keep the documents available to the Authorities and possibly provide them upon request.

11 VALIDITY AND RENEWAL OF THE VOLUNTARY CERTIFICATE

The validity of the Voluntary Certificate is specified directly in the Voluntary Certificate document. It is always associated with a duration of five (5) years. If, during the period of validity of the Voluntary Certification, the Manufacturer makes changes to the product to which the Voluntary Certificate relates, the Voluntary Certificate itself is no longer valid immediately.

When the expiration date is reached, the holder of the Voluntary Certificate can choose to keep it or not:

- the customer who decides not to renew the use of the voluntary certificate is required to remove any reference to the latter from any type of material to which it has been applied;
- to extend the validity period of the Voluntary Certification for another 5 years, CME must start a new evaluation procedure, applying the procedure referred to in chapter "Criteria for requesting the issue of voluntary certification from ECM and the process for obtaining it".

12 RENUNCIATION

At any time, the holder of the Voluntary Certificate may request to renounce it, by means of a written request, which he sends to ECM by email.

13 WITHDRAWAL (SUSPENSION) OF CERTIFICATES AND AUTHORIZATION TO USE THE VOLUNTARY CERTIFICATION

Voluntary certificates are withdrawn, suspended automatically with direct communication to the certificate applicant in the cases described below:

- if there is evidence that the product has changed after the issuance of the Voluntary Certificate;
- in the event of failure to notify ECM by the Manufacturer of changes in the name of the Holder of the voluntary Certificate or change of its headquarters;
- if there is evidence that the holder of the Voluntary Certificate is not applying this Regulation;
- Misuse of our name, our notification number 1282;
- Any changes made to the voluntary certificate.

14 COMPLAINTS, APPEALS (APPEALS) AND PROTESTS

14.1 COMPLAINTS

ECM takes into account and manages when it deems necessary written and verbal complaints from all parties with interest. ECM does not take into account any anonymous complaints, even if written.

The Director of Services and his staff perform an initial analysis of the complaint, to understand whether the complaint is founded or not.

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14.2 APPEALS (APPEALS)

Claims for compensation against decisions or documents issued by ECM must be submitted in writing by ordinary mail, fax or certified e-mail no later than 15 days after receipt of the document against which the interested party intends to appeal. No later than 5 working days after receipt of the request, ECM confirms that it will follow up and, if requested in writing, keeps the sender informed.

All claims are recorded by ECM in a register.

If the appeal refers to administrative-economic aspects, it is the Management and Commercial functions of ECM that carry out the verification of the customer's request. The acceptance or rejection of the request is communicated to the sender by the legal representative of ECM by certified mail, no later than 60 days from receipt.

If, on the other hand, the appeal is related to the procedure for issuing the Voluntary Certification, the Director of CME Services submits the verification of the Fabbricante's documentation for the issuance of the Voluntary Certification to a technician / team who did not take part in the initial procedures that led to the issuance of the Voluntary Certification itself. The results are then evaluated by the person responsible for issuing the Voluntary Certification itself (see "Criteria for requesting the issue of voluntary certification from ECM and the process for obtaining it"). No later than 90 days from receipt of the appeal, the legal representative of ECM communicates to the sender the result of the evaluation and, therefore, the acceptance or rejection of the appeal itself.

15 DISPUTES APPLICABLE LAW, JURISDICTION AND VENUE

(p.01) This agreement shall be governed by and construed in accordance with the laws of the "Republic of Italy".

(p.02) Any dispute arising from the execution and/or interpretation of this agreement will be submitted to the jurisdiction of the Italian Judge, where in this regard the parties identify the Court of Bologna as having exclusive jurisdiction to hear the dispute.

16 PRIVACY

All documents, letters, communications, etc., relating to the activities for the management of voluntary Certification on products belonging to the Manufacturer are considered private. Access to their consultation is allowed only to those who are involved in the procedure of issuing certificates and voluntary certification specifically on that product.

(p.01) Although no natural persons participate in this Regulation, the Parties declare in any case that they share and comply with the principles established on the processing of personal data by Regulation (EU) 2016/679 ("General Data Protection Regulation").

(p.02) In the event of the processing of personal data of natural persons, for any reason whatsoever in execution of these Regulations, the Parties hereby undertake to strictly comply with the principles and precepts of the aforementioned Regulation, with reference to any other personal data, including those of third parties, collected, stored, communicated, disseminated or otherwise processed in fulfillment of or as a consequence of this contract, in particular, ensuring scrupulous compliance with the provisions concerning security, consent and information relating to the data subject.

17 ACCEPTANCE CLAUSE

The " Acceptance of Rules on Voluntary Certificate (QAT10_M02)" form must be completed and signed by the Client.

18 LIST OF CME DOCUMENTS

18.1 Referred to in these Regulations

- *Note of the European Commission of 14 September 2022 Ref. Ares (2022) 6342894 (RGVOL01 -A2)*
- *List of Masters/Voluntary Certified Models and Markings (QAT10_Master)*
- *Acceptance of the Voluntary Certification Regulations, rules for the use of certificates and voluntary certificates (QAT10_M02)*

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