REGOLAMENTO PER LA CERTIFICAZIONE VOLONTARIA NON NOTIFICATA (PROCEDURA DI RILASCIO E ISTRUZIONI)
REGULATION FOR VOLUNTARY CERTIFICATION NOT NOTIFIED (ISSUANCE PROCEDURE AND INSTRUCTIONS)

APPROVAL FLOW				
ROLES ROLES	Name and surname (Name and surname)	Company function (business functions)	Date signed – MM/DD/YYYY (Signature date - MM/DD/YYYY)	Signature (signature)
Author (Author)	Gottardi Giovanni	Quality Assurance	01/16/2023	
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Approver (Approver)	Luca Bedonni	Sole Director	01/16/2023	

The approval flow refers to the approval of the following documents which form an integral part of these Regulations. The same are prepared by ECM and sent to the Applicant at the same time as the offers for the service are sent.

	Approved Documents	Reference
◆	RGVOL01	THIS REGULATION
◆	RGVOL01**-HY**	REVISION HISTORY
◆	QAT10_M02 _	Acceptance of the Voluntary Certification Regulations, rules for the use of certificates and voluntary certificates

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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), establishes 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 producers to ask ECM to issue voluntary certification;
- the ECM process for issuing this voluntary certification;
- how u be such voluntary certification.

Important Notes:

- The ECM company specifies that this is a "NOT NOTIFIED" activity;
- The manufacturer, under his sole responsibility, will be able to 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 activities for the issue of voluntary certificates 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 General Directorate for the Market, competition, consumer protection" and the " Technical Regulations Div. VII – Notified Bodies and Notification Authority accreditation systems - NANDO Contact Point for Italy ".

Issuance of the Voluntary Certificate " procedure is applied and performed by a "Department of the ECM Company" which DOES NOT INVOLVE the personnel 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 the "Voluntary Certification or Voluntary Attestation" is strictly connected to the terms set forth in these Regulations. The "Voluntary Certification" cannot be used before carefully reading these regulations.

These Regulations can be downloaded from the WEB Site – Ente Certificazione Macchine Srl

	WEBSITE	TO RESEARCH
	Home ECM (www.entecerma.it)	MACHINERY CERTIFICATION BODY SRL Customer Service > Official Documents > Regulations

1.2 Revision history

The history of the revisions is summarized in the document "History of Revisions (RGVOL01-HY)" same revision of this Regulation, and describes "List of Revisions, Approval Date, Reasons for the Revision". The History of Revisions is compiled upon approval of the Regulation to which it refers, and briefly summarizes the points affected by the modifications (Additions, variations, corrections, corrigendum).

2 APPLICABILITY

This Regulation applies exclusively to the activities performed by ECM, 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 or non-European Economic Area" without any discrimination.

For the release of the "Voluntary Certification" ECM 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 DISTRIBUTION

This regulation is available to interested parties on the ECM website (see " 1.1 Generality") , it is ECM's responsibility to make the updated version of these Regulations available on the website.

The specific Flow-Charts prepared by ECM form an integral part of these Regulations.

4 DEFINITIONS

Definition	Full definition
VOLUNTARY CERTIFICATION	It is the official expression of the results of the assessment of the submitted documentation, aimed at demonstrating compliance with the requirements of specifically identified standards / regulations [hereinafter "CC"].
CERTIFICATION HOLDER	organization that has requested and obtained the release of voluntary certification by ECM.
COMPLAINT	form of dissatisfaction, both verbal and written, on the services provided by ECM.
APPEAL (OR APPEAL)	formal deed, in the name of the subject, having specific causes, against the decisions taken or the evaluation expressed by ECM.
CC	Output of the assessment of the requirements carried out by the ECM Company in execution of each order and is released on a voluntary basis, substantially on the basis of the request of the Customer, which operates in the interest of a final user (ie the producer);

5 WHAT IS THE VOLUNTARY CME CERTIFICATION

(p.01) The Company undertakes to carry out only and exclusively activities for the issue of voluntary certificates 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 General Directorate for the market, competition, consumer protection and technical regulations Div. VII - Notified Bodies and accreditation systems Notification Authority - NANDO Contact Point for Italy .

(p.02) In formulating the order, the Customer undertakes to provide the Company with appropriate technical documentation to be analyzed subject to verification and with the standards and/or directives and/or regulations with respect to which the verification is required [hereinafter "Technical Documentation"], in order to put the Company in a position to perform its services correctly and in any case at best.

(p.03) The Company's activity will consist of a verification of the Technical Documentation made available by the Customer 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 certification [hereinafter " CC"]. always in compliance with the note of the European Commission of 14 September 2022 Ref. Ares (2022) 6342894.

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

(p.03.01) The CC is the output of the requirements assessment carried out by the Company in execution of each order and is released on a voluntary basis, essentially on the basis of the Client's request, which operates in the interest of an end user (i.e. tell the manufacturer);

(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 ***received*** .

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

(p03.04) The "Voluntary Certification Regulation Acceptance (QAT10_M02)" form must be completed, signed and stamped by the "Purchaser" and returned together with the order form to ECM.

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

For these reasons, the output of this documentation check 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.

6 PURPOSE OF THE CERTIFICATION/VOLUNTARY CERTIFICATE

The purpose of Voluntary Certification is to demonstrate (with the level of confidence associated with independent third party verification) that it meets ECM standards or specifications. This aim is achieved through an evaluation of the technical documentation, carried out before the release of the voluntary certification.

7 CONDITIONS FOR USE OF CERTIFICATION/VOLUNTARY CERTIFICATE

Voluntary Certification:

- It has NO legal standing, unless used between private companies with specific agreements between them;
- 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 cannot 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 regulation. The documents issued by ECM can only be mentioned in the same words used by ECM and in complete form, including the date of issue;
- It is NOT an authorization by ECM to apply CE certification to a product;
- It DOES NOT originate from customs requirements or to demonstrate to the authorities the conformity of the products to the requirements for the CE marking;
- It CANNOT be used to demonstrate product compliance to the Authorities;
- CANNOT be used during Government inspections;
- It may only be used for purposes authorized by law.

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

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

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

The "Certificate issued by ECM as Notified Body" is associated with a completely different purpose than that of the "Voluntary Certificate": the "Voluntary Certificate" has nothing to do with the certificates issued by ECM as Notified Body. Do not confuse these two types of certificates: if in doubt, contact ECM.

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

In case of doubts about the use of the "Voluntary Certificate", do not use them and contact ECM: info@entecerma.it

8 FEATURES AND DESIGN OF THE VOLUNTARY CERTIFICATION

The format of the "Voluntary Certification" is a "Rectangle with Rounded Edges", with the "ECM 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" cannot be modified in form, color or content. Its dimensions can be modified, but maintaining the same proportions as in the example of “Figure 1”.

In particular, the size 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.

See " List of Masters/Volunteer Certified Models and "QAT10_Master" Markings for all types of logos .

Figura 1

8.1 Types of Certificates

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 Models and "QAT10_Master" Markings) .

9 CRITERIA FOR REQUESTING ECM THE RELEASE OF VOLUNTARY CERTIFICATION AND THE PROCESS FOR OBTAINING IT

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

They are issued with reference to a documentary analysis and subject to verification by an ECM employee; they are released only if, according to 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:

1. Request by the Client for the feasibility of issuing a voluntary certificate;
2. Acceptance of ECM and preparation of the economic offer;
3. Acceptance of the offer by the customer and shipment of the order to ECM;
4. Verification of documentation by an ECM technician;
5. Once the verification of the documentation by a Technical Expert has been completed, a CC will be prepared for a positive assessment by the verifier and checked by the RT before approval by the Legal Representative.
6. The person designated within the organization as legal representative of LR of ECM will sign and issue the CC as responsible for the approval and issue of the voluntary certification.

10 RESPONSIBILITIES AND RIGHTS

10.1 Specific obligations to be paid by the Client

10.1.1 Holder of the Voluntary Certification

The owner of the voluntary Certification is solely responsible for its use.

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

10.1.2 Using the Certification

Must use the Certification according to the rules set out in chapter " 7- Conditions For Use Of Certification/Voluntary Certificate" of these Regulations;

- in general, they must behave and act in compliance 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 given in the chapter " 9 - Criteria For 9ECM Criteria For Requesting ECM The Release Of Voluntary Certification And The Process For Obtaining It" . of this Regulation;
- may not allow others to use the Voluntary Certification on behalf of the holder;
- they cannot associate any slogan of the holder of the Certificate with the voluntary Certification;
- may not combine the Voluntary Certificate with any other logo or certification which could change its meaning or be misunderstood by the end user of the Certificate;
- they can never combine voluntary certification with mandatory certification, which can only be used by accredited organizations and an accreditation body;
- must ensure that all prospective end-users of commercial, advertising and promotional material referencing the Voluntary Certification do not misunderstand the scope of the Voluntary Certification itself, thinking that it applies to products or activities outside the actual scope of the Voluntary Certification ;
- may not use the Voluntary Certificate in a way that damages ECM's reputation and compromises the trust of all possible interested parties;
- must be available for any additional verification requests by ECM.

The holder of the voluntary certificate can (rights):

- use the Voluntary Certificate under the conditions and according to the rules mentioned in this document. This right is no longer valid after the expiration date of the certificate;

- use the Voluntary Certificate for internal use (within the Voluntary Certification Holder's company) or externally for voluntary demonstration purposes.

10.2 Responsibilities And Rights Of E CM

10.2.1 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 meant:

- **Professional Secret** : 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, (i) whose actual or potential economic value arises from not being generally known and not readily ascertainable by other persons who may derive economic value from their disclosure or use, and (ii) is made reasonable efforts under the circumstances to maintain secrecy;

- **Confidential Commercial 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 financial positions of the Company 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.

10.2.2 Commitment to Confidentiality

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

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

(p.03) The Parties may disclose Professional Secrets or Confidential Commercial Information of which they are aware only in response to a binding request from the Judicial Authority or other Public Bodies, following a legal proceeding which requires the disclosing party to do so, provided that the request to disclose professional secrets or confidential commercial information in this way gives time to allow the Company and/or the Client to seek an adequate protection structure.

(p.04) In the event that the Client violates or threatens to violate the provisions of this chapter, the Company will be entitled to a fair compensation that takes into account all damages directly and indirectly suffered for the disclosure and/or use of confidential information pursuant to the this agreement.

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

10.3 Responsibility of ECM

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

(p.02) The CC and, in general, the activity carried out by the Company, will be bound by the request formulated by the Customer, by the information provided by the same and by the Technical Documentation, so that in no way can the Company receive objections regarding the object of the verification and insights completed.

(p.03) Initiate an investigation into any complaint or notice from the market, according to the instructions given in chapter " 15- Complaints, Appeals (APPEALS) And Protests" of these Regulations and, if deemed necessary, withdraw the voluntary certificate;

(p.04) In the event that ECM detects or is informed of the presence of a false Certification on the market, it publishes the document on its website ("false certificates" section) 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.

10.4 Express Termination Clause

This regulation shall be deemed terminated by law pursuant to " art. 1456 of the Italian Civil Code ", in the event of written communication with which the Company expresses its intention to make use of this clause, in the following cases:

- violation by the Customer of the payment terms referred to in the payments chapter;
- violation by the Customer of the confidentiality obligations referred to in the chapter " 10.2- Responsibilities And Rights Of E CM";
- violation by the Customer of one or more provisions of this regulation;
- subjection of the Client to any bankruptcy procedure, or equivalent procedure envisaged under Chinese law.

10.5 Payments Clause

The Management of ECM can 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 set 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. Without prejudice to any deferred payment agreements, which must be authorized by ECM Management.

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

11 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 ECM database after the issue of the Certificate / Voluntary Certification.

It is the responsibility of the Manufacturer to keep the documents available to the Authorities.

12 VALIDITY AND RENEWAL OF THE CERTIFICATE VOLUNTARY

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 refers, the Voluntary Certificate itself is no longer valid immediately.

When the expiry 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 period of validity of the Voluntary Certification for another 5 years, ECM must start a new evaluation procedure, applying the procedure described in the chapter "9 - Criteria 9Requesting Criteria For Requesting ECM The Release Of Voluntary Certification And The Process For Obtaining It".

13 WAIVER

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

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

Volunteer certificates are being retired

- if there is evidence that the verified documentation no longer complies with the requirements of the reference ECM;

- if there is evidence that the product has changed since the issuance of the Voluntary Certificate;
- in case of lack of communication to 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;
- in the event of changes to the requirements of the relevant Directives / Regulations (taking into account the times allowed by the Directives / Regulations themselves to comply with the new requirements);
- in the event of notification by the Product Detection Authorities of any non-compliance with the essential requirements of the reference Directives / Regulations.

15 COMPLAINTS, APPEALS (APPEALS) AND PROTESTS

15.1 COMPLAINTS

ECM takes into account and manages the written and verbal complaints of all parties with interest.

ECM does not take into account any anonymous complaints, even if written.

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

15.2 APPEALS (APPEALS)

Claims for compensation against decisions or documents issued by ECM must be presented in writing by ordinary mail, fax or certified e-mail no later than 15 days after receipt of the deed against which the interested party intends to appeal. Within and no later than 5 working days from 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, the Commercial and QA functions of ECM carry out the verification of the customer's request. The acceptance or otherwise of the request is communicated to the sender by the legal representative of ECM via certified mail, no later than 60 days from receipt.

If, on the other hand, the appeal relates to the procedure for issuing the voluntary Certification, the Director of ECM Services submits the verification of the Fabbricane documentation for the issue of the voluntary Certification to a technician / team who did not take part in the initial procedures which led to the issue of the voluntary Certification itself. The results are then evaluated by the person in charge of issuing the voluntary Certification itself (see " 9- Criteria For Requesting ECM The Release Of Voluntary Certification And The Process For Obtaining It"). No later than 90 days from receipt of the appeal, the legal representative of ECM notifies the sender of the result of the evaluation and, therefore, whether or not the appeal itself is accepted.

16 DISPUTE GOVERNING LAW, JURISDICTION AND JURISDICTION

(p.01) This agreement is governed and interpreted in accordance with the laws of the "Italian Republic".

(p.02) Any dispute deriving 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.

17 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 for issuing certificates and voluntary certification specifically on that product.

(p.01) Although natural persons are not involved in this Regulation, the Parties declare in any case to share and respect the principles established on the subject of personal data processing by Regulation (EU) 2016/679 ("General Data Protection Regulation").

(p.02) In the event of processing of personal data of natural persons, for any reason in execution of this Regulation, 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 treated in fulfillment or as a consequence of this contract, guaranteeing in particular the scrupulous observance of the provisions concerning security, consent and information relating to the interested party.

18 ACCEPTANCE CLAUSE

The "Acceptance of Rules on Voluntary Certificate (QAT10_M02)" form must be completed, signed and stamped by the "Purchaser" and returned together with the order form to ECM.

19 ECM DOCUMENT LIST

19.1 Referred to in these Regulations

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

ALLEGATI
ATTACHMENTS

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RE REGOLAMENTO PER LA CERTIFICAZIONE VOLONTARIA NON NOTIFICATA (REGULATION FOR VOLUNTARY CERTIFICATION NOT NOTIFIED)

REVISION HISTORY (CHANGELOG)

PARENT CODE	RGVOL01		APPROVAL FLOW	
ROLES ROLES	Name and surname (Name and surname)	Company function (business functions)	Date signed – DD/MM/YYYY (Signature date - DD/MM/YYYY)	Signature (signature)
NOTE	THIS DOCUMENT IS JOINTLY APPROVED TO THE DOCUMENT **RGVOL01**REFERRED TO IN THE SAME VERSION			
For He confirms	Gotthard John	Quality Assurance	**16/01/2023**	See Document **RGVOL01 Ver. 02**

Memorandum Rules for managing revision history

The **History of Revisions** is compiled upon approval of the procedure to which it refers, and briefly summarizes the points affected by the changes (Additions, variations, corrections, corrigendum).

Date of Distribution/Publication Date : Refers to Date of replacing “DRAFT” with “APPROVED” in the document header.
Training Field: If equal to “ **YES** ” indicates that Training follows after the distribution of the document. The type of training is defined according to what is established in the procedure " **QAT_05** " the type of training to be used. If equal to "No" it indicates that the Training is not deemed necessary.

Exclusions : The History of Revisions is not compiled in cases of "spelling corrections and/or graphic improvements"; more generally it is not compiled in all cases in which the modifications made do not change in any way "the principles, rules, requirements and references" contained in the procedures.

REV.	Distribution Date Publication Date	Changes Compared to Previous Version Change in Front to the Previous Version	Training Yes/No
0	01/11/2022	New emission	NO
1	01/11/2022	New module added, and paragraphs 8.0, 8.1 updated - QAT10_Master REV.00 - List of Certificate Models Unified module with "RGVOL01_A01 REV.00" with "QAT10_M02" as they are equal - Acceptance of the Voluntary Certification Regulations, rules for the use of certificates and voluntary certificates (QAT10_M02)	NO
2	01/16/2023	Various amendments to align the regulation to the flow of voluntary certification activities (Paragraphs 9, 18) as well as Correction of typos and errors	NO
-	-	-	-
-	-	-	-
-	-	-	-
-	-	-	-
-	-	-	-

Ref.Ares(2022)6342894

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR INTERNAL MARKET, INDUSTRY, ENTREPRENEURSH AND SMES
Networks & Governance
D.3 – Market Surveillance

Brussels, 14 September 2022
grow.d.3(2022)7036064

NOTE FOR THE ATTENTION OF MARKET SURVEILLANCE AUTHORITIES AND NOTIFYING AUTHORITIES

Subject: Voluntary certification for products subject of EU technical harmonisation legislation

Some market surveillance authorities have brought to the attention of the Commission and other authorities that a practice of 'voluntary certification' exists for some products, which are subject of EU technical harmonisation legislation (namely for PPE, Medical Devices, ATEX, RED and PED), especially during the COVID-19 crisis. However, later the application of this practice has been noticed for a number of other harmonised products, including very dangerous products (such as machines used in explosive environments, civil explosives or pyrotechnic articles) for which participation of a notified body in the conformity assessment is always necessary.

While the websites for such 'voluntary certification' usually indicate that this activity is not performed in the capacity of the certification body as notified body as such, and it is usually presented as something similar to a 'quality marking', the notified body number has been used in some cases on such documents (whereas the body is not notified for the products in question), these documents are called certificates, and very often the CE marking is present on these documents issued[1]. This is not compatible with the Union product legislation as detailed below, as such a practice leads to confusion and misunderstandings on the effective value of such documents, including also uncertainties about the effective safety and compliance of the concerned products.

It is also to be noted that the terms *certification*, *independent third party* and similar have a specific meaning as it comes to harmonised Union product legislation, essentially related to the work carried out by notified bodies in their capacity and according to the relevant conformity assessment procedure(s), and their use for other types of assessments of products falling under this legislation may be misleading. *Certificate* is a document issued by a body that takes responsibilities in areas of public interest. Therefore, if a Union product legislation does not provide for a third-party involvement in the

[1] The European Safety Federation (ESF), which groups national associations of manufacturers, importers and distributors of Personal Protective Equipment in Europe prepared a list of such certificates and published it on its website: https://www.eu-esf.org/covid-19/4513-covid-19- suspicious-certificates-for-ppe

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conformity assessment but the economic operator opts for a voluntary involvement of a third party, the document issued by that third party could bear the name 'certificate' only if the body involved on a voluntary basis is a notified body for the specific area. A notified body may carry out activities in areas where it is not notified (for example, in non-harmonised areas or when products are intended for third countries); but it has to clearly mention that these activities are not in the scope of their notification under harmonised Union product legislation, as notified by the competent authorities and listed in the Commission's NANDO information system and these activities cannot be in an area of harmonised Union product legislation which requires assessment by a notified body. The notified body cannot use its notified body number in relation to assessments, tests, certificates or other activities for the legislation it is not notified for. The non- notified activities may not overlap with the notified ones, they must be clearly distinguished from the notified ones, they may not create confusion and they must be clearly mentioned as "non-notified"; otherwise the notifying authority must take appropriate action.

The notified body must have policies and procedures that distinguish between the tasks it carries out as a notified body and any other activity in which it is engaged, and it must make this distinction clear to its customers. Accordingly, marketing material must not give any impression that assessment or other activities carried out by the body are linked with tasks described in the applicable Union harmonisation legislation. Also to be emphasized that CE marking is only to be affixed after testing the product and performing the prescribed conformity assessment procedure or procedures according to the applicable Union harmonisation legislation. For some product legislation[2] and for medium-high risk products[3], involvement of a notified body is mandatory – the manufacturer cannot perform the assessment alone, nor use of a non-notified conformity assessment body is enough either to issue the EC/EU declaration of conformity or to affix the CE marking.

Article 30(2) of Regulation (EC) No 765/2008 states that *the CE marking <...> shall be affixed only to products to which its affixing is provided for by specific Community harmonisation legislation, and shall not be affixed to any other product*. Article R12(1) of Decision 2008/768/EC, which is integrated in most of the pieces of sectoral legislation[4], foresees a possibility to affix the CE marking to the packaging or the accompanying documents only if fixing it to the product or its data plate is not possible and if the product legislation provides for such documents. Therefore, it is not acceptable for such 'voluntary certificates' to bear a CE marking.

Article 30(5) of Regulation (EC) No 765/2008 states that *the affixing to a product of markings, signs or inscriptions, which are likely to mislead third parties regarding the meaning or form of the CE marking, shall be prohibited*. Clearly, this is the case for 'voluntary certificates' bearing CE marking. Such a 'certificate' leads to understanding that the product is in conformity with applicable Union legislation, however the 'voluntary certificate' is issued without any product checks and is not foreseen in any of the legislation. As stated on the concerned websites, it is usually issued following documentation checks only.

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[2] Directive 2013/29/EU on pyrotechnic articles, Directive 2014/28/EU on civil explosives

[3] Regulation (EU) 2016/425 on personal protective equipment, Regulation (EU) 2017/745 on medical devices, Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices Directive 2013/29/EU on pyrotechnic articles, Directive 2014/28/EU on civil explosives; under Directive 2014/53/EU on radio equipment, it is mandatory for certain requirements, if relevant harmonised standards do not exist or are not applied.

[4] Article 20(41) of Directive 2013/29/EU, Article 23(1) of Directive 2014/28/EU, Article 19(1) of Directive 2014/53/EU (CE marking on the packaging is always mandatory)

Article 30(6) of Regulation (EC) No 765/2008 obliges Member States to *take appropriate action in the event of improper use of the marking. Member States shall also provide for penalties for infringements, which may include criminal sanctions for serious infringements.*

Article R34(1)(a) of Decision 2008/768/EC, which is integrated in most of the pieces of sectoral legislation, requires that where a Member State finds that the conformity marking has been affixed in violation of Article [R11] or of Article [R12], it shall require the relevant economic operator to put an end to the non-compliance concerned. Article R34(2) further requires that where such the non-compliance persists, *the Member State concerned shall take all appropriate measures to restrict or prohibit the product being made available on the market or ensure that it is recalled or withdrawn from the market.*

Taking into account the above:

(1) **Market surveillance authorities** are requested to take notice of the above and check their respective markets for products, which bear incorrect documentation and, subsequently, take appropriate action. Special attention is to be paid to conformity assessment of products. All products falling under harmonised Union product legislation for which conformity assessment procedures foreseen in the respective legislation have not been followed, shall be taken off the market and this shall be considered as a serious infringement by the economic operator.

(2) **Notifying/designating authorities** are requested to also take notice of the above and make sure that the bodies they have notified or designated are not performing any misleading activities using their notification, also that they use their notified body number properly and only for the sectors they are notified for. The activities outside the scope of technical harmonisation legislation of the notified bodies should not compromise or diminish confidence in their competence, objectivity, impartiality or operational integrity. Where the notification is misused, a withdrawal of notification shall be considered.

Commission reserves the right to also take any necessary action to challenge the competence of notified bodies involved in such practices, or to withdraw their notification by using the specific provisions laid down in EU harmonisation legislation[5].

(e-signed)
Matthias SCHMIDT-GERDTS Head of Unit

[5] For instance, Article 31 of Regulation (EU) 2016/425 on personal protective equipment, Article 47 of Regulation (EU) 2017/745 on medical devices, etc.

PAGINA LASCIATA INTENZIONALMENTE BIANCA

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RILASCIO DI CERTIFICAZIONE VOLONTARIA NON NOTIIFCATA (RELEASE OF VOLUNTARY CERTIFICATION NOT NOTIFIED)

Elenco Master/Modelli "Certificati Volontari" e "Marcature"

FLUSSO APPROVATIVO (APPROVAL FLOW)				
RUOLI ROLES	Nome e cognome (Name and surname)	Funzione aziendale (Business function)	Data firma – GG/MM/AAAA (Signature date - DD/MM/YYYY)	Firma (Signature)
Autore (Author)	Gottardi Giovanni	Vice Assicuratore Qualità	27/10/2022	
Ufficio Tecnico Revisore (Reviewer)	Ravara Gian Luca	Strategy Technical Consulting	01/11/2022	Approvato incontro del 01/11/2022, firma apposta da QA per riscontro
Approvatore (Approver)	Bedonni Luca	Amministratore Unico	01/11/2022	Approvato incontro del 01/11/2022, firma apposta da QA per riscontro

Tipologia/Master	Descrizione	Marcature
Modulo Format 1 di Certificato Volontario	Certificate of Compliance Directive (2006/42/EC Machinery, 2014/35/EU Low Voltage, 2014/30/EU Electromagnetic Compatibility, MDR Class 1, 2014/53/UE Radio Equipment).	
Modulo Format 2 di Certificato Volontario	Verification of Compliance Directive (2014/34/UE ATEX, 2014/68/UE Pressure Equipment, 2014/33/UE Lift).	
Modulo Format 3 di Certificato Volontario	Attestation of Compliance Directive Regulation (General Product, 2016/425/UE DPI, CPR 305 Material construction). Solo DPI 1 categoria e prodotti esclusi da quelli certificati con procedura da Organismi Notificati.	
Modulo Format 4 di Certificato Volontario	Attestation RoHS Directive (2011/65/EU amended by 2015/863/EU RoHS).	
Modulo Format 5 di Certificato Volontario	Certificate of compliance with ETSI standards	
Modulo Format 6 di Certificato Volontario	Certificate SIL Functional Safety of compliance with IEC standards	

MODULO DI ACCETTAZIONE REGOLE SU CERTIFICATO VOLONTARIO

The Applicant / Manufacturer XXXXXXX declares to read the following rules before using the ECM voluntary certificate and to apply them:

1. Both the manufacturer and the applicant declare that they have read and understood and accepted the Regulations (document code: **RGVOL01_ECM**) on the issue of voluntary certificates which can be consulted on the Ente Certificazione Macchine srl website www.entecerma.it .
2. The voluntary certificate does not represent a certification process, but only a documentary verification carried out on a voluntary basis of the technical documentation received and immediately returned as it contains sensitive data at the end of the activity performed.
3. The voluntary certificate is the output of the assessment of the requirements carried out by the Machine Certification Body in execution of each order and is issued on a voluntary basis, substantially on the basis of the Customer's request.
4. The voluntary certificate is not to be used either for customs purposes or to demonstrate to the Authority the conformity of a product with the requirements of the Directive / Regulation / other reference legislation. The voluntary certificate cannot be used to export and/or enter products within the European Union as it is not a CE Certificate of Conformity nor does it replace the CE Declaration of Conformity. Both the manufacturer and the applicant declare that they are perfectly aware of the nature of the same and that it absolutely cannot be used to replace the EU/EC declaration of Conformity which must be issued exclusively by the manufacturer and cannot be used to place products on the market within the European Community
5. The certificate is voluntary and is intended for use among professionals who are perfectly aware of the possibility of its use and its value.
6. The reference voluntary certificate is NOT required by any law (it is voluntary) and is intended for commercial use between private companies. This voluntary certificate is NOT a legal requirement to apply the CE marking on the product.
7. The manufacturer is responsible for compliance with the legal requirements relating to CE marking.
8. The user of voluntary certificates is responsible for its use and for making appropriate use of it in compliance with the legislation in force in the countries in which it is used. This certificate has no legal value.
9. The certificates issued by ECM as a Notified Body have completely different uses than the voluntary ones. The voluntary certificates have nothing to do with the certificates issued by ECM as a Notified Body. Don't confuse the two types of certificates; if in doubt, contact ECM.
10. **This document must always be delivered together with the voluntary certificate as an attachment. Using the certificate without this attached document is neither permitted nor acceptable.**

Manufacturer
X ACCEPTANCE AND ACKNOWLEDGMENT (date, signature and stamp)

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Applicant
DATE SIGNATURE X ACCEPTANCE AND ACKNOWLEDGMENT

_____

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