

# GENERAL PRODUCT CERTIFICATION REGULATION



Version 2

Date: 03.02.2023

Code: KAN 02

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# GENERAL PRODUCT CERTIFICATION REGULATION

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## 1. GENERAL INFORMATION

#### 1.1 The Certification Body

ERGOCERT HELLAS SA is an independent Certification Body (CB). Product certification services concern the assessment and the certification of a product, a process or a service, and meet the requirements of EN ISO / IEC 17065 :2012 and ESYD.

Through the assessment and certification process, it is possible to confirm the compliance of products-services-processes with the certification requirements regarding qualitative and quantitative characteristics, safety issues, suitability for use and continuous compliance during operation, as defined in relevant legislative / regulatory documents, standards or certification schemes and contracts. For the tasks that CB receives, it has the necessary technical competence and the required personnel.

The General Product Certification Regulation provides general information, defines the certification procedure and the cooperation between the customer and ERGOCERT HELLAS SA, and it is publicly available on the CB's website.

Responsible for the implementation of this General Product Certification Regulation is the Technical Director of the CB in collaboration with the Quality Manager. The Quality Manager is responsible for issuing and revising it always with the approval of the Administration.

ERGOCERT HELLAS SA reserves the right to modify the General Product Certification Regulation at any time.

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#### 1.2 Object

The provision of assessment and certification services includes the following types and areas of products:

Elevators	Initial check	Directive 2014/33/EE K.Y.A. 39507/167/F.9.2 (Official Government Gazette 1047/B/13-04-2016)
Electric lifts	-Examination type "EE"	-Annex IV <sub>B</sub> , Section B
	-Final check	-Appendix V
	-Compliance based on unit verification	-Annex VIII, Section Z
Hydraulic lifts	-compliance based on unit vernication	- ELOT EN 81-20:2014
		- ELOT EN 81-21:2009+A1:2012
		- ELOT EN 81-22: 2014
		- ELOT EN 81-28:2003
		- ELOT EN 81-50: 2014
		- ELOT EN 81-58:2003
		- ELOT EN 81-70:2004
		- ELOT EN 81-71:2005+A1:2007
		- ELOT EN 81-72:2003
		- ELOT EN 81-73:2005
		- ELOT EN 12015:2014
		- ELOT EN 12016:2013
		- ELOT EN 13015:2001+ A 1:2008
Pressure equipment	Internal production control and supervised pressure	Directive 2014/68/EU
	equipment checks at random intervals	Y.A No. house 74124/DTBN 1431/2016 (Government Gazette 2278/B/2016)
	EU type examination - production type	(Government Gazette 2278/B/2016)
		Annex III, Section A2
	EU type examination - design type	
	Conformity to type based on internal production	Annex III, point 3.1, Section B
	control and supervised pressure equipment testing at random intervals	Annex III, point 3.2, Section B,
	Conformity to type based on verification on pressure equipment	Annex III, point 4, Section C2
	Compliance based on unit verification	Annex III, point 9, Section F
		Annex III, point 10, Section G



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## 2. REGULATORY TEXTS

- ✓ EN ISO/IEC 17065:2012 Conformity Assessment Requirements for bodies certifying products, processes and services
- ✓ ISO/IEC 17000:2004 , Conformity assessment Vocabulary and general principles

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- ✓ ISO/IEC 17067:2013, Conformity assessment Fundamentals of product certification and guidelines for product certification schemes
- ✓ ESYD KAD, as applicable each time
- ✓ ESYD CRITERIA Accreditation Criteria, as applicable each time
- ✓ ESYD DD Accreditation Procedures, as applicable each time
- ✓ EA-2/17 M: 2020 EA Document on Accreditation for Notification purposes
- Regulations and Guidelines of the ESYD by field of Accreditation and situations in accordance with what is mentioned in the Special Regulations and Work Instructions
- ✓ IAF Instructions (MD-ID) in accordance with what is mentioned in the General Product Certification Regulation and the Special Regulations and Work Instructions per certification standard or scheme.
- ✓ Certification Standards and Schemes, as listed in table 2.1.
- ✓ Applicable Legislation Texts of Greece and the European Union, as listed in table 2.1.

# 3. TERMS AND DEFINITIONS

- impartiality: presence of objectivity (as objectivity is determined when there are no conflicts of interest or when they are resolved so that they do not negatively affect the subsequent activities of the CB
- confidentiality: maintaining the confidentiality of records or information, as well as adhering to agreed activities within the wider framework of trust
- standard: is a document, drawn up by consensus of the technical committees of the respective reference field and approved by a recognized body, which provides rules, guidelines, or characteristics for common and repeated use for activities or their results, with the aim of achieving the best degree class in a specific application context
- CE marking: marking by which the manufacturer declares that the product complies with the applicable requirements of Community harmonization legislation, which provides for the affixing of the marking
- notified body: a certification body which a competent Authority of a Member State of the European Union has notified to the European Commission in the context of the implementation of a specific New Approach directive
- inspector / auditor: person who conducts an assessment / inspection
- certification: is the process of third-party confirmation that refers to products, processes, schemes or even persons. The term third-party confirmation means the written declaration validation (issuance of a certificate), by the independent body that provides the object to be assessed for conformity with recognized competence, regarding the characteristics of a person or organization or product, that the verification of the specified requirements, has been adequately documented
- certification assessment /inspection: is the assessment / inspection carried out by an Certification Body independent of the customer and the parties relying on the certification, with the aim of certifying the product-process-service
- certification scheme: certification scheme in which the same specific requirements, specific rules and procedures apply
- non-compliance: failure to fulfill a requirement
- Q.M.S.: Quality Management System
- Q.M.: Quality Manager
- CB: Certification Body
- E.SY.D.: Hellenic Accreditation System

## 4. IMPARTIALITY, INDEPENDENCE AND CONFIDENTIALITY

## 4.1 Impartiality and Independence

The CB, as defined in its statutes, does not maintain any type of relationship (commercial and/or financial) with other Companies/Organizations, which may jeopardize the impartiality of its decisions and it is not involved in activities that may jeopardize its impartiality.

It is CB's policy to provide certification services in a way that ensures its independence and impartiality, to strengthen market confidence about its work and for this reason an Impartiality Committee (D14) has been established.

Access to the services of the CB is free for all interested organizations and/or persons, regardless of ownership or size, while the processing of requests for assessment is carried out in an equable manner without discrimination. All customers and interested parties are not subject to excessive and/or unjustified financial and/or other conditions and are treated equally in a spirit of mutual respect and equity.

The executive staff of the CB and the respective Committees that have been established have no relationship with the organizations on whose behalf the inspections/ assessments are carried out and they are not allowed to maintain any commitment that could affect the objectivity of their judgment and their impartiality.

The CB, its staff, the Inspectors/Assessors, as well as the members of the respective Special Committees are free from any commercial, financial or other pressures and commitments, which may affect the correctness of their technical judgement.

The CB and its staff are in no way, directly or indirectly, involved and not related to activities of design, manufacture, supply, installation, purchase, ownership, representation, use and/or maintenance of the objects under assessment.

Inspectors/ Assessors do not provide any advisory, training, or expert services as part of an assessment.

The fees of the staff participating in the activities related to the inspections / assessments, do not depend on, and are not related to the results of these assessments.

# 4.2 Confidentiality

The CB undertakes to maintain the confidentiality of all information disclosed or provided by the client and to evaluate them only for the agreed purpose of certification. Documents produced by the customer are not granted in any way to third parties, except the Notifying Authority and the Accreditation Body or the bodies that assess the Accreditation Body. Exception would be the possible enforcement of non-observance of confidentiality by law, administrative act, court decision in case where a detailed reference to a legal dispute is required or in case where the competent state authority supervising the process requests information in writing. In these cases, the customer involved is also informed for the information shared.

The CB operates in compliance with the provisions of European Regulation 679/2016 (GDPR).

## 4.3 Non-Discrimination Policy

The CB procedures and policies do not discriminate with respect to the services provided. The services are publicly described through the website and social media. Any interested organization can submit the application for certification that is available from the CB.

Access to regulations and certification information is provided to all organizations regardless of size and scope.

The CB may reject a certification application if it is proven that the client is involved in illegal activities or has a history of repeated non-compliances.

## 5. FINANCIAL INDEPENDENCE – FEES

For the certification services offered by the CB there is civil professional liability coverage.

Necessary condition for the conduct of assessments and the granting of the corresponding certificates is the timely fulfillment of the customer's financial obligations to the CB, regardless of the outcome of the assessment.

Assessment fees are specified in the financial offer - contract for the certification service signed between the CB and the customer.

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#### 6. ASSESSMENT PROCEDURE

## 6.1. Application for Certification – Offer for Certification – Offer Acceptance

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Prospective customers request a Certification Offer from CB by completing an application and attaching the required documentation. The application and the information material (Certification Regulations) are received by the customer either directly from the CB or through its website (<u>www.ergocert.gr</u>).

The CB examines and reviews the application to verify the completeness and accuracy of the data and prepares the offer for the certification assessment.

Certification activities do not begin unless the customer has accepted the offer - contract through the signature. By means of the offer - contract acceptance, the provisions of the General Regulation and any Special Regulations are also accepted.

## 6.2. Assessment Scheduling

After signing the offer - contract, the CB agrees with the customer on the period for carrying out the assessment. The assessment is carried out according to the schedule. It is best that the assessment/inspection date is agreed in writing at least 10 days in advance.

The signing of the offer-contract does not constitute a direct or indirect certification obligation.

The CB designates the inspectors / assessors and informs the customer. Depending on the type and quantity of assessed products / services / processes, the CB may assign the assessment to a group of inspectors / assessors.

#### 6.3. Conducting an Assessment

The conduct of the assessment includes the assessment of the conformity of the product-service-process in accordance with the requirements of the scheme, legislation, agreement, standards, etc. and according to planning.

To carry out the assessment, the customer must facilitate by providing the necessary samples, technical files, free access to the facilities to be assessed, to the personnel involved, to the relevant documentation and to all kinds of records related to the object under assessment.

For certification services defined in a regulatory provision (Greek or Community), is required the implementation of all the relevant provisions of the legislation, as they have been recorded in the relevant procedures, instructions, the present General Regulation and the corresponding Special Regulation.

The assessment may consist of:

- Supervision of production
- Supervision of product testing
- Conduct product testing
- Assessing and verifying the fulfilment of requirements for the product/service/process individually or in batches
- Assessment of the adequacy of the client's premises, equipment, personnel.
- Verification of product design compliance, etc.

The assessment is carried out according to the procedures, instructions, regulations of the CB or according to the design in case of control according to the customer's requirements. In any case, all findings are documented by completing special documents (checklists). Upon completion of the assessment, the inspector / assessor presents the results to the client and writes the Report based on them.

In the event of deviations from the requirements of the assessed object, the Report is communicated to the customer to remedy any observations / non-conformities. Re-assessment of the product, additional on-site inspection or submission of appropriate documentation to the CB may be required to confirm the remediation of non-conformances.

The customer of the assessed product, service, process bears full responsibility for any damage that occurs during the assessment procedure and from the operation of the product or the installation. The CB has civil professional liability coverage for any errors and omissions of its staff during the provision of services.

## 6.4. Certification Decision - Issuance of the Certificate

After the assessment has been carried out, the customer receives the Report and the Certificate, which is signed by authorized personnel, after the review of all information and the results of the assessment has been carried out, the relevant decision has been issued by a competent person of the CB who is not involved in the assessment. The information review and certification decision are completed simultaneously and documented.

The content of the Report and the Certificate and the duration of validity are determined by the relevant legislation, standards and the CB procedures defined for the specific certification scheme.

Reports / Certificates may not be used in a way that could be characterized as misleading by the Accreditation Body.

The granting of an accredited Report / Certificate does not constitute or imply approval by the Accreditation Body.

In case of non-granting a certificate, the CB informs in writing about the decision not to grant certification and specifies the reasons of this decision.

## 6.5. Surveillance

If surveillance is required by the certification scheme, CB carries out a surveillance inspection in accordance with the respective certification scheme, legislation, standard, etc.

## 6.6 Conducting a Periodic Assessment

An assessed product-process-service can be re-assessed upon customer's request and according to the requirements of the certification scheme/legislation etc.

## 6.7 Conduct of Emergency Assessment

The CB has the right to request an emergency assessment when changes are found in the assessed object, to investigate complaints to the competent authorities from an interested party, there are changes in the relevant legislation or the verification of the implementation of the corrective actions is required. When carrying out emergency assessments, what is defined in the relevant procedures is followed and the customer is obliged to provide all the necessary facilities.

#### 6.8 Modification of Certification Scope

The customer can request a modification, extension, or limitation of the certification scope by submitting the corresponding application. The CB examines the application following the same procedure as in the case of the original application.

## 7. RETENTION OF CERTIFICATES

In the case of <u>one-time issuance</u> of certificates for products that concern a specific product at a specific time and place, the customer is obliged to maintain the certificate for the entire duration of its validity.

In the case of certificates concerning process, service, product design or installation, the customer (manufacturer or owner) must inform the CB of any change in the scope of the audit. With the notification of any changes, the CB re-assesses the compliance with the applicable requirements and in these cases the customer is not allowed to use the issued certificate until receiving relevant information from the CB.

Accordingly, the CB also informs the customer in case of changes in the certification requirements by specifying the effective date of validity of the changes and the need for an additional assessment of the certified object, in order to launch the necessary changes for compliance with the new requirements. The customer must notify the CB within a specified period of time of his

intention to accept the changes. If there is an acceptance of the changes by the customer and the results of the assessment are positive, the CB will issue a supplementary certificate. If there is no acceptance of the changes within the predetermined time by the customer or the results of the assessment are not positive, the certificate will cease to be valid on the effective date of the changes.

It is not permitted to reproduce part of the Report / Certificate, only in their entirety upon approval by the CB.

## 8. SUSPENSION, REVOCATION OF CERTIFICATE

The customer has the right to request the suspension/revocation of a certificate. For this purpose, he applies a request to the CB. Suspension of a certificate is the temporary ban on the use of the certificate, while revocation is its complete withdrawal and deletion from the CB registers.

In cases of suspension/revocation of a certificate, the CB has the right to inform any third party, while it is obliged to inform the competent state authorities, when the certification concerns regulatory provisions.

The CB revokes the certificate for the following reasons:

- The customer does not follow the rules described within the General Regulation, the supplementary Special Regulations, and the relevant contract.
- The customer does not disclose to the CB of any changes to the scope of certification that may affect the product's compliance with the predetermined requirements.
- The customer makes bad and misleading use of the certificate and any marks / logos.
- The customer voluntarily requested the revocation of the certificate for reasons not related to the CB.
- Prohibition / penalty has been imposed on the customer, related to the certification, by law, administrative act, court decision
  including the Accreditation bodies.
- The customer surveillance assessment, where it is foreseen, did not have a positive outcome or could not be conducted for reasons not related to the CB.
- The customer did not pay the relevant certification fees to ERGOCERT HELLAS SA within the prescribed deadline. In this case,
   CB reserves the right to pursue the satisfaction of its claims in any legal way and means, judicially and extrajudicially.
- The customer generally became insolvent, stopped paying or went out of business.
- The client changes scope or field of activity.

The CB can impose a suspension (temporary revocation) of a certificate as a warning or for reasons possibly specified in the Special Regulations. The suspension of the certificate and its cause as well as the conditions for compliance and removal of the suspension are communicated to the customer with a certain response date. In case of non-response, the certificate is revoked.

In cases of suspension or revocation of the certificate, the right to use the certificate and any relevant mark / logo by the customer is automatically terminated. An inspection/assessment with positive results must precede the reissuance of a certificate.

A reduction in the scope of certification may occur at the request of the customer or it could be found by the CB during the assessment that pre-defined requirements are not met.

Withdrawal, revocation of a certificate or reduction of the scope of certification is not a cause of financial claims from the customer.

## 9. COMPLAINT

Anyone can submit complaints about any management of the CB, which can be considered not in accordance with the standards, but also the persons who represent them.

Such complaints should be submitted in writing and forwarded to the Technical Director and Quality Manager.

For valid complaints about the certification process, the CB informs the Impartiality Committee and the Administration of the CB.

The CB undertakes to inform the complainant about the outcome of the complaint. Anonymous complaints are not taken into account by the CB.

## **10. OBJECTIONS - APPEALS**

Anyone can file an objection/ appeal against any decision of the CB which has arisen after an assessment, including the decision to suspend and revoke the certification. The objection/ appeal must be sent by letter to CB within 30 days from the notification of this decision. The CB will provide written confirmation of receipt of this objection/ appeal.

For the investigation and decision on the objection/ appeal, the Objections & Complaints Committee is set up, as stated, and applies to the cases of complaints. The Committee includes members of the Administration and employees who are not involved in the specific case referred to in the objection/ appeal, to preserve impartiality.

If the objection/ appeal is related to a discriminatory attitude of the CB, the Impartiality Committee is informed.

The CB submits the objection/ appeal to the special committee, which takes a reasoned decision. The final decision is issued within 30 days from the submission of the objection/ appeal. The person submitting the objection/appeal is informed in writing with a copy of the Commission's decision within 2 working days of its issuance.

#### **11. OBLIGATIONS OF PARTIES**

#### 11.1 Obligations of the Certification Body

The CB assesses the product-service-process according to the relevant requirements and in case of a positive result, issues a certificate. The CB undertakes to implement exclusively the scientific, technical, empirical, and logical rules, which are applied, and it is not bound by orders, instructions, and suggestions of the mandator or others for the exercise of its duties.

The CB must inform customers of significant changes in the certification process/scheme that directly affect them.

The CB informs the customer about the presence of observers during the assessment, who may be inspectors / assessors under training or assessors of the Accreditation Body.

The CB maintains an updated register of certified products-services-processes, in which are included information about the certified product-service-process, the scope of certification/control (standard, legislation, regulation, technical requirements, etc.), the customer's details, the validity period of the certification, as well as a list of certificates that are suspended or revoked. The CB, upon written request, must inform any interested party of the status and scope of a specific certificate, unless otherwise provided by law.

The CB must accept and record customer complaints and objections in order to manage them according to its procedures.

All the CB staff, including external partners, are committed to independence, impartiality, and confidentiality by signing Declarations of Independence and Confidentiality and the Code of Ethics.

The CB has the appropriate systems in place and implements data security policies aimed at protecting the managed information and customer files.

When issuing a product-service-process certificate, the CB assigns to the customer the right to use it exclusively and only for the scope described in it.

## 11.2 Obligations/Rights of Customers and use of logos/marks and Certificates

The applicant for certification is considered by definition to be authorized to assign work to the CB (the one identified as a customer) and has the obligation to inform it in advance in case of non-authorization for disposal, handling, use, maintenance etc. of the object under assessment.

The customer is obliged to fulfill the certification requirements (certification scheme), including the additional actions-changes that will be required by the CB and the body that accredit it.

The customer has the possibility to reject the inspectors / assessors appointed by the CB, as long as there is a documented justification.

The customer must make all necessary arrangements for the assessment of documentation and records relating to the certification, and access to its relevant equipment, facilities, personnel, and subcontractors.

The customer must accept during the assessments the presence of observers, who may be inspectors / assessors under training or assessors of the Accreditation Body. The customer is informed in advance about the presence of these persons.

The customer has the right to request clarifications on the standards and other regulatory documents relating to the compliance requirements of the certification scheme, however the CB will be limited to information that does not constitute consultancy to the customer, while any formulation of a technical opinion will be using appropriate and impartial experts who have the necessary competence and jurisdiction.

The customer should inform the CB no later than within one month about changes that may affect the product-service-process compliance with the certification requirements. In case it is deemed necessary, at the discretion of the CB, a new assessment will be carried out.

The customer has the obligation to keep and make available to the CB all the results of audit authorities, complaints, and objections from interested parties, as well as the way they are managed, related to the scope of certification.

The customer must mention the certification exclusively for the field that is certified by the CB (product, service, etc.).

The customer must not use the certification in a defamatory way for the CB or misleading.

In case of suspension, revocation or expiration of the certification, the customer should stop any promotion related to the certificate and take the appropriate measures, which will be communicated to him by the CB, regarding the marked product.

In case the customer provides copies of the CB certificates to third parties, then these copies must be complete and identical to the original.

The customer must comply with the requirements of the certification scheme regarding the use of logos, marks and product/service/process information.

In case the customer wishes to renew/withdraw his certificate, he is obliged to inform the CB in writing.

## 12. CHANGE AND REVISION OF CERTIFICATION REGULATION

The change and revision of this General Product Certification Regulation is under the jurisdiction of the CB and its Administration. The change and revision of the Regulation is carried out by the Quality Manager and approved by the CB's Administration.