

# ATEX PRODUCT CERTIFICATION REGULATION



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## 0. INTRODUCTION

- 0.1 EUROCERT EUROPEAN INSPECTIONS AND CERTIFICATIONS CLIENT S.A., is a private client that is activated in a National, European and International level.
- 0.2 EUROCERT does not involve itself in any way in the provision of consultancy services regarding the organisation and application of the relating standards to the interested parties.
- 0.3 EUROCERT's independence is assured by its Constitution, its organisational structure and the Certification Committee's operation.
- 0.4 EUROCERT treats all companies in an equal manner and co-operates with them under the exclusive subject of good interpretation and application of the Standards and this regulation.

### USED APPREVIATIONS

- IAF** : International Accreditation Forum
- P.C.C** : Product Compliance Certificate
- I.T.** : Inspection Team
- C.C.C.** : Catalogue of Certified Companies
- R.C.C.** : Register of Certified Companies
- C.C.** : Certification Committee

## ARTICLE 1 : SCOPE

- 1.1 This document has been written in the form of a Regulation, in accordance to the internal procedures that are applied by EUROCERT and comply with the requirements of the Standards ISO/IEC 17065 and EN ISO/IEC 17020 as well as the guiding instructions of the IAF. The present Regulation defines the responsibilities of the companies as well as those of EUROCERT for the procedures concerning the issue, monitoring, extension, pause, renewal and recall of the PCC. A client's certification automatically assures its registration in the Catalogue of Certified Companies, CCC.
- 1.2 The Regulation has been approved by EUROCERT's Managing Director and each amendment ought to be approved by him. In cases of amendment, the applications that have been submitted are reviewed by the Secretary, the non-informed clients are identified according to the current issue and they are sent the valid issue which is recorded on the application.
- 1.3 The implementation of this Regulation is supervised by the Certification Committee. The latter is an independent to EUROCERT Committee in which interested parties to the certification in the sector of products/ services are represented. The Certification Committee has defined its representatives of the following organizations to examine the subjects concerning the certification of products / services:

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- Representative of SEV ( Hellenic Industry Association)
- Representative from EK.POI.ZO (Consumer Association)
- Representative of the Benaki Phytopathological Institute
- Representative from E.P.P.E.(Union of Environmental Scientists )
- Member of the Board of EUROCERT

- 1.4 The necessary requirement for a client to be granted the PCC is that the produced items comply with the requirements of this Regulation, the requirements defined in EUROCERT's relevant procedures and the requirements defined by Legislation (Hellenic and European).
- 1.5 The client ought to inform EUROCERT, during the inspection, about the requirements defined by Legislation (Hellenic and European).
- 1.6 The procedure for issuing/ awarding a PCC is carried out according to the valid inspection and certification procedures for the products/ services.

### **ARTICLE 2 : RELATED DOCUMENTS**

- 2.2 ISO/IEC 17065 «Conformity assessment — Requirements for bodies certifying products, processes and services»
- 2.3 ISO/IEC 17020 “General criteria for the operation of various types of bodies performing inspections”
- 2.4 IAF/ILAC A4 «Guidance on the Application of ISO/IEC 17020»
- 2.5 EA-2/17: 2009 - EA Guidance on the horizontal requirements for the accreditation of conformity assessment bodies for notification purposes
- 2.6 M.D. F23/11267/547/09.01.15 “Decision authorization / notification of the Body by the Ministry of Development and Competitiveness”
- 2.7 2014/34/EU - Relating to equipment and protective systems intended for use in potentially explosive atmospheres (recast)

### **ARTICLE 3 : DEFINITIONS**

All terms and regulations used in this Regulation are in line with EN 45020.

The term “client” applies to all organisations, as well as individuals that request the inspection and the certification of a product.

### **ARTICLE 4 : GENERAL REQUIREMENTS**

- 4.1 All companies irrespective of size or scope may submit an application to EUROCERT regarding product certification.

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- 4.2 All applications are evaluated in line with procedure ΔΠ6.1 and the corresponding product/service procedure. For the former to be accepted and for the inspection and certification procedure to commence they ought to be accompanied by the necessary documents as stated in the corresponding procedure.
- 4.3 EUROCERT's Management as well as personnel (permanent staff and external associates) deal all incoming information during the certification process as highly confidential and adhere to the Code of Ethics.
- 4.4 The interested client ought to know that all documents that are issued by EUROCERT are the latter's property and as such any further duplication and distribution to third parties without the latter's permission is prohibited.

### **ARTICLE 5: SUBMISSION AND HANDLING OF APPLICATION FOR EVALUATION AND CERTIFICATION**

- 5.1 The client ought to submit an application to EUROCERT in accordance with the special application form and the required technical file.
- 5.2 The application ought to be dully filled in.
- 5.3 Each submitted application concerns only one product/ service category. The submitted application stands as a contract apart from the cases where a separate contract document exists and its duration is defined by the re-assessment date as listed on the PCC.
- 5.4 Immediately after the submission of the application the evaluation procedure commences according to the relevant procedures in which the contents of the application and the attached documentation which has to comply with the corresponding reference standard are checked.
- 5.5 During the application examination, EUROCERT's accredited schedule and notification status, where required, are considered. In case the applied inspection standard is covered by notification but it is not mentioned in the official schedule issued by the accreditation body, then the standard is used as technical specification for checking the design of the product but not mentioned on the certificate.
- 5.6 In the event of an acceptance of the application, an Inspection Team is called upon to perform the inspection. The client documents his/her acceptance of the inspection/audit team by either returning to EUROCERT a signed inspection program or by signing the Visit Form. In the event the application is not accepted the interested client is informed in written.
- 5.7 The Inspection/Audit Team, I.T./ A.T., consists of one, or more Inspectors/ Auditors, employed or associated that have been approved by EUROCERT's Board of Directors, based on the requirements defined in the International Standards and occasionally

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by technical expertise. The formation of the team occurs in such a way that it is in a position to evaluate the special technical requirements of the product.

- 5.8 The technical experts may come from Public Organisations, Legal Parties of Public Right, Legal Parties of Private Right, Educational Institutions, Technological/ Research Centres, and Businesses etc. In each case the inspections dates and the inspection team are announced in advance to the interested client the latter of which is asked for their confirmation.
- 5.9 When external associates are used, EUROCERT takes all proper measures to assure the objectivity, the integrity, and the confidentiality. In any case, the interested client has the right to ask for the replacement of a member of the Inspection Team.
- 5.10 The client is bound to allow the free access of the Inspection/Audit Team to all areas or product areas and to provide all the related to the inspection documents and to ease the inspectors by providing them where necessary with the relevant personnel.
- 5.11 The inspection of the products is described in the corresponding product certification procedures.
- 5.12 In cases where sampling is required, the received samples are sealed and marked and are forwarded to the appropriate laboratories on applicant's costs. In the case sampling is executed in an uninformed inspection mode, then the frequency of the sampling is annual and one sample is taken per product type selected from those ready to be dispatched.
- 5.13 In cases where destructive or non-destructive testing is required, these are performed by accredited laboratories and according to instructions designated by the relevant manufacturing standards. Especially for the laboratories abroad, those have to be selected from the accreditation bodies web sites in the countries they are based and for the relevant per case scope.
- 5.14 EUROCERT will be using accredited laboratories for conducting tests for ATEX products. EUROCERT reserves the right to witness all or part of the tests at the laboratory site and witness those tests not conducted by the laboratory at the manufacturer's site. Non accredited laboratories shall not be accepted.
- 5.15 In cases where deviations are observed either from the requirements of the products or the corresponding procedures and the present regulation, EUROCERT does not issue / award a PCC.
- 5.16 The interested client ought to repair, amend, fill-in the deviations/findings of the performed inspection for it to be issued with a PCC. If required upon occasion, the correction of the findings occurs with an onsite inspection/audit by the I.T./A.T.
- 5.17 The Technical Director on the basis of the inspection/audit results and the outcomes

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of the laboratory tests and after verification of the corrective actions by the I.T./ A.T., examines if the product conforms to the requirements of this regulation, the corresponding reference standards and the relevant procedures and decides accordingly upon the issue of the PCC.

- 5.18 The client must a) keep a record of all complaints made known to the supplier relating to a product's compliance with requirements of the relevant standard and to make these records available to EUROCERT when requested, b) take appropriate action with respect to such complaints and any deficiencies found in products or services that affect compliance with the requirements for certification, c) document the actions taken.
- 5.19 EUROCERT reserves the right to reissue a revised report or PCC where mistakes have been spotted after it has already been issued to the client for further submitting to the competent authority.

### **ARTICLE 6: CERTIFICATION AND REGISTRATION IN THE CATALOGUE OF THE CERTIFIED COMPANIES**

- 6.1 The decision for the issue of a PCC is the due responsibility of the Technical Director. The Certification Committee then validates the decision.
- 6.2 The Certification Committee validates the decisions of the Technical Director at a later date than the initial granting of the PCC. The operation rules and the responsibilities of the Certification Committee are defined in the relative regulation and EUROCERT's Quality Manual.
- 6.3 If the Certification Committee rejects the validation, a Special Inspection/Audit is carried out for EUROCERT to verify the Committee's remarks. In the event that no compliances are observed, Art. 9.2 of this Regulation is in effect. This type of special inspection's/audit's associated cost is carried by EUROCERT.
- 6.4 After the issue of the PCC, the client and the product are registered into the CCC as well as into EUROCERT's web catalogue of certified clients on: [www.eurocert.gr](http://www.eurocert.gr). The CCC includes the client's name, the category, or the type of the products that are defined by the PCC's field of application. The CCC also includes the standard according to which the evaluation and certification took place, as well as the PCC's date of issue.
- 6.5 EUROCERT does not release to any third party any documents related to certification cases or control of product of client without client's written consent and permission. In the event that a competent authority requests information, the client is informed prior to any disposal of the information. ESYD within the accreditation of EUROCERT, like any other competent accreditation body and only in this case, as governed by a code of ethics for the protection of client privacy, may have access to



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client case files. No other information other than those listed in 6.4, permitted to enter into shared access.

6.6 EUROCERT is shall provide the other bodies notified under 2014/34/EU carrying out similar conformity assessment activities covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results

### ARTICLE 7 : RECERTIFICATIONS AND RENEWAL OF PCC

- 7.1 The validity period of the PCC is stated on the PCC. Two months before its expiration, the client may apply for recertification.
- 7.2 Recertification requires an onsite visit. The recertification requirements are defined in the corresponding product EUROCERT procedures.
- 7.3 The certified client must inform EUROCERT during the PCC validity period of any changes which may affect its ability to comply with the requirements of certification. Such changes can be any change in manufactured products, in production processes, the equipment used, etc. EUROCERT after being updated by the client decides whether to conduct a site inspection or require further detailed information from the client.
- 7.4 The certification committee reserves the right to perform a re-check of the product in the event that further special checks or tests are needed. The corresponding costs in this case are covered by EUROCERT.

### ARTICLE 8 : Certification Extension / Suspension / Withdrawal / Reduction of Scope

#### 8.1 Extension of Scope

The client must submit a new application or a letter for extension and revised relevant documentation.

An extension to scope audit can be performed independently of the client's surveillance plan or combined with one of the planned surveillance audits.

Following steps of Article 5 of this and a new contract (if required) and a new certificate issued.

#### 8.2 Suspension / Withdrawal / Reduction of Scope

EUROCERT has the right to put in suspension the certificate if:

- The client is systematically unable to follow the requirements of the standard and

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this regulation

- The client denies the conduction of the audits for the interval which is determined from EUROCERT
- The client has asked for the interruption of the Certification
- The Certification Committee requires the recall when the client failures to comply with of the present proceeding.

In this case, a time interval of not than more six months is given to the client to comply with the requirements of the reference standard and this regulation.

If at least one of the above still holds and the client is unable to resolve the problem then EUROCERT may ask for the withdrawal of the client's certificate or the reduction of its certification scope.

Additionally, EUROCERT withdraws the certificate in case it has been imposed by EUROCERT's Certification Committee, after non-compliance with this Regulation.

For all the above, the Client must be informed in written as well as the relevant Directorate of the Ministry of Development.

### **ARTICLE 9 : COMPLAINTS - APPEALS**

9.1 The client or other interested party may raise a complaint or appeal against EUROCERT's decisions in written within thirty days from the notification of the decision.

#### **9.2 COMPLAINTS**

9.2.1 Any member of staff may receive a complaint of any kind, by the client or other interested party. It is required to complete the form ΔΠ18.1/E01, attaching if any, the complaining party's related letter, email or FAX and forwards them to the Quality Manager.

9.2.2 The Quality Manager, together with the relevant Director, review the complaint and determine if required to do corrective action, when the ΔΠ19.3 applicable.

9.2.3 The person related to a complaint will not take part in the evaluation of the subject complaint.

9.2.4 In the event that the complaint is correct, a copy of the form ΔΠ18.1/E01 is forwarded to the Managing Director. The Quality Manager sends copies to all interested departments and Directors.

9.2.5 If during the evaluation of a complaint, no deficiencies in Eurocert's quality system or case handling manner are spotted, the Quality Manager then informs the client

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accordingly in written. If the complaining party is not satisfied by the response, it has the right to appeal the decision in accordance to the provisions of paragraph 9.3 below. Otherwise, all appropriate measures are taken immediately for solving the problem and the complaining party is informed accordingly with the actions taken in written. All financial implications in the case are covered by EUROCERT.

### **9.3 APPEALS**

- 9.3.1 When there is an appeal against EUROCERT's decisions, the Quality Manager completes the form ΔΠ18.1/E01, attaching the relevant FAX, email or letter by the appealing party.
- 9.3.2 In order EUROCERT to receive and examine an appeal, it must have been submitted within one month of notification of the decision in question.
- 9.3.3 The Quality Manager, after consultation with the Director related to the issue, will examine and accept or reject the appeal. The Managing Director is informed by the Quality Manager for all actions involved.
- 9.3.4 If the appeal is accepted, EUROCERT amends its decision and the client is informed in written. The Quality Manager also informs the Managing Director and directly apply corrective action to remedy the problem and the non reappearance of this, based on procedure ΔΠ19.3. The effectiveness of the corrective action is verified by the Managing Director himself. In this case all corrective actions to be taken will be covered financially by EUROCERT.
- 9.3.5 If the appeal is rejected, the appealing party shall be notified accordingly and the decision remains valid.
- 9.3.6 The decision on the acceptance or not of the appeal must be issued within three months of its submission, unless the interested party or national legislation or the competent authority imposes different.
- 9.3.7 The appealing party and EUROCERT, if not satisfied, have the right to address to a Court of Arbitration in accordance with the provisions of the Civil Procedure Code.

### **ARTICLE 10 : FINANCIAL TERMS**

- 10.1 Before the PCC is issued, the client ought to have paid in full the entire fee as agreed at the stage of application.
- 10.2 The laboratory costs are directly paid to the testing laboratory by the client.