ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ
ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ
ΣΤΗΝ ΥΓΕΙΑ Α.Ε.

NATIONAL EVALUATION CENTER
OF QUALITY & TECHNOLOGY
IN HEALTH S.A.

CERTIFICATION REGULATION

OF QUALITY SYSTEMS AND MEDICAL DEVICES

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Introduction

The present General Regulation of Assessment and Certification of Quality Systems and Devices concerns the assessment and certification of quality systems and medical devices. It presents the procedure and the conditions of granting,maintenance and renewal of Certificates for Quality Systems and Devices, the rights and the obligations of the National Assessment Center of Quality and Technology in Health and of the owners of certificates, and the current financial conditions. It constitutes a text that must be complied with by any client who signs an agreement for the certification of the quality system installed, and / or the manufactured devices.

1. Presentation of National Assessment Center of Quality and Technology in Health

National Assessment Center of Quality and Technology in Health (E.K.A.P.T.Y. SA.) is an institution supervised by the Ministry of Health and Social Solidarity and it is governed by the law 3429/2005 and 2190/1920. Its legal framework and organizational structure ensure its independence and impartiality.

National Assessment Center of Quality and Technology in Health is the new name of the company under the name "Research Center for Biomaterials SA." and the distinctive title E.KE.V.YL. SA, which since 1997 operates as a Certification Body and Notified Body for Medical Devices, with identification code 0653, accredited by ESYD for the activities of certification for quality systems and medical devices.

National Assessment Center of Quality and Technology in Health (E.K.A.P.T.Y. A.E.) grants quality certificates indicating conformity of devices, services, processes and quality systems with the requirements of National, European and International standards and Legislation.

The assessment and certification of conformity of the Quality System of an organization is accordant to the requirements of standard EN ISO 9001 as well as the specialized standards and Ministerial Decisions that concern institutions activatedin health sector. Assessment and certification of conformity of medical devices is made as to the requirements of Directive 93/42/EEC and the Ministerial Decision harmonizing the national legislation, ΔΥ8δ/Γ.Π.οικ.130648.

EKAPTY operates in accordance to the requirements of the standards:

a) ΕΛΟΤ EN ISO/IEC 17065 «Conformity assessment - Requirements for bodies providing certification of products, processes and services"

b) ΕΛΟΤ EN ISO/IEC 17021 "Conformity assessment - Requirements for bodies providing audit and certification of management systems"

and carries Civil Liability coverage for the certification activities offered.

2. Quality System Certificate

Quality System Certificate means that the certified organization has established and maintains a quality system, which ensures that the produced devices and services are of constant quality in relation to the requirements that have been stated.

3. Certificate of Conformity of Device – CE Marking

The Certificate of Conformity of Device and grant of marking CE 0653 means that the certified device is produced in a manner that complies with the requirements of applicable Legislation.

4. Impartiality, Independence, Integrity

EKAPTY operates as an independent Certification Body of Quality Systems and Medical Devices. Its independence and impartiality is ensured by the legal framework of its establishment and operation, financial independence, the operation of the Independent Certification Council (I.C.C.) and organizational structure.

To ensure the integrity, objectivity and impartiality, EKAPTY has also adopted the following settings:

- The staff is not involved in any way in the planning, organization and implementation of quality system for the organizations assessed.
- The staff is not involved in the design, manufacture, supply, representation, installation and maintenance of medical devices.
- EKAPTY staff involved in the assessment and certification procedures, has no financial, commercial or other relationship with the organizations assessed or their commercial competitors.

- EKAPTY cooperates with the organizations concerned only as to the correct interpretation of Standards and Legislation.
- Any person or organization interested in the certification has seamless access to certification services of EKAPTY.
- The current certification regulations, price lists and related information documents are freely accessible to all interested parties.
- Decisions on certification of organizations and devices are taken by persons not involved in the assessment process.

5. Confidentiality

EKAPTY ensures privacy and confidentiality to its clients at all levels of its operation. The I.C.C. and all involved partners are responsible for managing documents, data, and any information that will come in their perception or possession during their cooperation with EKAPTY as of strictly confidential nature. This information will be used only for the purpose of implementation of the project they undertake.

Specifically:

- EKAPTY handles in strict confidence any document and / or device of its clients found in its possession. All information and contents of documents and / or electronic data that may come to the knowledge of the institution and / or its auditors remain absolutely confidential. To this end, all Board members, staff, external partners and the members of the Independent Certification Council commit to respect the independence and confidentiality.
- All the auditors and staff of EKAPTY operate strictly within the institution's proceedings and are bound by the Code of Ethics.

Where the availability of information to a third party is legally required, EKAPTY informs the client.

Exception to the above is the information of the Competent Authority as it is a legal obligation of notified bodies to communicate their findings to National Drug Organization -EOF (Ministerial Decision. ΔΥ8δ/1348/04).

6. Independent Council of Certification

The Independent Certification Council (I.C.C.) of EKAPTY which is established by a decision of the Board of Directors, operates in accordance with the Rules of

Operation ICC and is convened under the responsibility of the President in cases of objections or appeals in order to give an expert opinion.

The I.C.C. ensures impartiality with regard to the decision-making, through the equivalent representation of stakeholders in its composition, without dominating any of the participating parties or interests.

7. Granting Certificate of Quality System

The procedure for granting Quality System Certificate includes the following steps:

a. Application
b. Assessment
c. Approval
d. Grant

a. Application – Signing of Agreement

a.1. Any organization seeking certification (hereafter referred to as "client") submits to EKAPTY an application for assessment of the quality system implemented, receives the current Certification Regulation and is informed of the cost of certification.

a.2. Then submits to EKAPTY the quality manual and related documents and signs a contract of conformity assessment of the quality system. The structure and the exact content of this contract are determined per case.

Signing of the contract by the client declares his agreement with the Regulation and the conditions set out in that contract.

b. Assessment

The assessment of the quality system in respect to the applicable requirements is performed in accordance with the standard EN ISO / IEC 17021 and the guidelines of ESYD of EA and IAF

b.1. for the certification of a quality system the following are assessed:

- its conformity with the legislation requirements or the relevant standard through which the assessment will take place
- the implementation and effectiveness, in terms of objectives and quality policy of the organization and applicable legal and regulatory requirements. Certificate of Conformity to the ministerial decision ΔΥ8/1348/04 may be

granted only on the basis of the existing infrastructure, without requiring previous system implementation. The exception is due to the mandatory nature of the legislation and the clear corresponding provision for such possibility

b.2. the assessment of a quality system (initial audit) is done in two stages:

- *Stage 1:* involves review of documentation (quality manual, technical documentation, applicable standards and procedures), review of legal and regulatory requirements and confirmation of performing both internal audit and management review of the quality system. The purpose of the first phase is to determine if the system is applied to a sufficient extent so that they can carry out the second phase which is the main audit. Where it is considered appropriate part of the first phase of the assessment is done at the client premises.
- *Stage 2:* audit at the client premises
- The interval between the two phases depends on the findings of the first phase. The client is informed in writing for the audit plan.

b.3. The assessment is done by an appropriate audit team, which consists of the Lead Auditor and, where appropriate, one or more auditors and / or technical experts, depending on the scope and size of the organizations to be audited. Audit teams are formed so as to have the necessary knowledge, expertise and experience in regard with the applicable legal and audit requirements.

The client is informed in writing for the composition of the audit team.

EKAPTY guarantees the impartiality and objectivity of the auditors, however the client has the right to request in writing the replacement of a member and / or member of the audit team if there are serious reasons and substantiate the relevant request.

b.4. Upon completion of the audit, a closing meeting is performed, during which the audit team informs the client for the audit findings and gives him the audit report, which includes the conclusions of the audit and the technical opinion on the fulfillment or not of the requirements

Failure of compliance to a specified requirement is defined as non conformity.

During the stage 1 audit, nonconformities are not recorded. The issues that could potentially lead to nonconformity during the stage 2 audit, are identified so as to be addressed.

The client is required, either at the closing meeting or after that, to state possible comments and describe the corrective actions to be taken within a specified period for the successfully address of the non-conformity identified.

Confirmation of the successfully address of the non-conformity can be done by performing a new full or partial audit. Should the completion of corrective actions require a longer period than that of two months, there will be a total re-audit of the organization.

The audit report and all relevant documentation are delivered by the Lead Auditor to the Certification Department of EKAPTY.

c. Decision

c.1. The granting or not granting of the Quality System Certificate follows the decision of the Certification Committee, which consists of the head of the certification department, a lead auditor ce mark and a technical / clinical evaluator.

c.2 . EKAPTY grants the Quality System Certificate when the ability of the client's management system to meet the requirements and achieve its objectives is evidenced.

c.3 . The decision is made based on the assessment of the audit findings and conclusions and any other relevant information, such as potential comments by the client.

d. Granting

Provided that the decision of the Certification Committee is positive, the Quality System Certificate is granted.

The Quality System Certificate certifies that the client has established and effectively implements a quality system that meets the requirements of the legislation or standards upon which it has been certified.

The Quality System Certificate only concerns the client this has been granted to and only the processes and domains covered thereby.

If the Quality System Certificate covers only a part of the manufactured devices and services or activities of the organization, the organization must notify its clients for the devices and services that are not covered by the Quality System Certificate.

All documents issued by EKAPTY and being part of the certification process are property of EKAPTY.

8. Granting a Device Conformity Certificate - CE Marking

The process of granting a Device Conformity Certificate (CE marking) includes the following steps:

a. Application

b. Assessment

c. Approval

d. Granting

a. Application – Signing of the agreement

a.1. The company interested in certification submits to EKAPTY an application for conformity assessment of the manufactured devices, receives the present Certification Regulation and relevant information to the cost and the certification process .

a.2. Thereafter, the company submits the Technical File of its device(s), The Quality Manual and the relevant documentation and signs the contract for the assessment. The structure and the exact content of this contract shall be determined as appropriate. The technical documentation must meet the requirements set by EKAPTY .

b. Assessment

The assessment is always implemented in two phases:

- 1st phase: it includes the review of legal and regulatory requirements, documentation control (technical file, relevant quality standards, quality manual) and where applicable, on site visit
- 2nd phase: audit at clients premises

b.1. Technical record assessment. All the technical documentation for the products under production is submitted by the client to EKAPTY. For class III products, the

client submits all the relevant documentation for the product design, the production and the product efficacy, as well as all the relevant documentation to prove the conformance to the defined requirements. The technical file is evaluated by a special scientist (or by a technical committee) who has the appropriate knowledge, expertise and experience in the particular subject

If the assessment is assigned to an external partner, EKAPTY informs the client in writing. EKAPTY guarantees the impartiality and objectivity of the assessors, but the client has the right to apply for replacement if there are serious reasons and should substantiate the relevant request.

Upon completion of the assessment, the results are communicated to the client in writing.

The process ends when following the submission of all the additional tests andrelevant evidence, the client covers all deficiencies / discrepancies that may bedetected and the assessment shows that the device meets the applicablerequirements. EKAPTY grants the Design Examination Certificate (according to point c), in which the prerequisites of certificate validation are clearly stated

For class IIa and IIb products, assessment of the technical documentation of a representative sample is carried out. EKAPTY performs sampling in terms of similarities related to design, technology, production and sterilization methods, as well as the intended use of the product. b.2. Assessment Audit. The assessment audit is performed in accordance with those described in Chapter 7.b. of this Regulation.

c. Decision

The granting or not granting of Device Conformity Certificate follows the decision of the Certification Committee, which consists of the head of the certification department, a lead auditor ce mark and a technical / clinical evaluator of EKAPTY.

After the completion of the aforementioned procedures, the Certification Department submits the assessment report to the Certification Committee and a decision is made within a month. EKAPTY grants a Device Conformity Certificate following evidenced satisfaction of all the required criteria.

d. Granting

If the decision of the Assessment Committee is positive, the Device Conformity Certificate and the CE marking are granted.

The Device Conformity Certificate and the CE marking granted by EKAPTY certifies that the device meets the essential requirements of Directive 93/42/EEC and KYA ΔΥ8δ/Γ.Ρ.οικ.130648.

The Device Conformity Certificate and the CE marking relates exclusively to the device covered thereby and the client this has been granted to.

All documents issued by EKAPTY and being part of the certification process are property of EKAPTY.

9. Certification Maintenance

a. General

Maintaining a quality system and device certificate and requires the continuous conformity of the client to the obligations arising from the certification.

For this purpose EKAPTY performs regular surveillance audits which may be scheduled or non-scheduled.

A surveillance audit may be a full system audit (all data of the quality system and / or device technical file are audited) or partial (audit of specific parts of the system). If the surveillance audits are partial, they are planned so that all data of the quality system and / or device technical file are audited at least once in the period of duration of the certificate.

Throughout the duration time of the device conformity certificate EKAPTY may also carry out tests and / or have them performed by third parties in order to monitor the continuous conformity of relevant devices.

If during the surveillance audits non-conformities are detected, they should be successfully addressed in a defined time period, accepted by the Certification Department of EKAPTY, which will assess, possibly with a new audit, the corrective actions. Following the expiration of this period, any failure to address the non-conformities stands as a cause for initiating a withdrawal process of the certificate. Repeated non-conformities detected in the previous audits that have not been addressed adequately, may be a cause for activation of the withdrawal process.

b. Frequency of audits

The frequency of audits is determined by the Certification Department of EKAPTY taking into account the findings of previous audits, the nature of the applied quality system, the device hazards and possibly information indicating inadequate implementation of the approved quality system. Surveillance audits are performed

annually at least. The first surveillance audit is carried out within 12 months from the date of the certification decision by the Committee.

If no surveillance audit is performed within the above mentioned period the certification is automatically suspended. The maximum period for waiving a suspension is six months. If during this period a surveillance audit is performed, the suspension is waived, except as stated in Chapter 16 of this Regulation. If a surveillance audit is not performed during the semester of suspension, the certification is withdrawn. .

Exceptions to the above may be decided by the Certification Committee upon substantiated request from the client.

c. Special Audits

A special audit is performed when:

- there are significant modifications to the quality system of the client, which may affect the conformity with the applicable requirements
- there is evidence to its necessity (e.g. denunciations, client complaints, violations detected by the Competent Authority etc.)
- there is doubt on the implementation of the planned corrective actions or the conformity with the legal requirements
- considered necessary by EKAPTY

and can be performed without prior notification of the auditee.

d. Unannounced Audits

For the clients certified after the Directive 93/42/EEC, unannounced audits will be performed, without prior notification, at a minimum of once per three years

Unannounced audits can also be performed at a client's major subcontractor or supplier premises, especially when the aforementioned subcontractor or supplier has undertaken important part of the production procedure.

During the unannounced audits, if considered necessary, testing implementationcould be asked to be performed, in order to ensure the functionality of the implemented quality system. Testing will be carried out by the client, at his premises, in presence of EKAPTY's auditors. Alternatively, in some cases, product sampling could be performed for tests and controls implementation, either in appropriate accredited laboratories.

e. Modifications

Throughout the duration of validity of the certificate the client is obliged to notify the Certification Department of EKAPTY of any proposed modification to the applied quality system, or type of devices manufactured. The Certification Department of EKAPTY assesses the importance of the proposed modifications and decides whether an additional assessment is required.

Indicatively, the following examples of major modifications are set forth:

- change of ownership or company site
- change of the persons in charge for the implementation of the quality system and / or device documentation
- change of location of the manufacturing processes and / or device quality control
- change of standards in terms of which the conformity of the device is verified
- adding of a new device group
- significant modifications to the applied processes.

The identification during the surveillance audit of substantial modifications to the applied quality system that were not updated in EKAPTY may be a reason forinitiating the certificate withdrawal process.

f. Expansion - Reduction of the certification field

It is possible for modifications to be made to the certification field throughout the duration of the granted certificate.

If the client wishes the expansion of the certification field, informs in writing the Certification Department of EKAPTY and an assessment audit of the new activity is scheduled. This audit may be combined with the surveillance audit or performed independently.

Moreover, the certification field can be shrank if found through the surveillance process that, regarding specific activity of the client, the requirements arising from certification aren't met or upon request by the client. In this case, the client is obliged to inform its customers of the devices and services that are not covered by the Quality System Certificate.

10. Certification Renewal

For the renewal of the certification, a full quality system audit is performed (all the data of the quality system and / or device technical file are audited). The purpose of

the re-audit is to confirm the client's continued conformity with the requirements arising from its certification.

If during the audits non-conformities are detected, they shall be waived in certaintime that is accepted by the Certification Department of EKAPTY, who will assess, possibly via a new audit, the corrective actions.

The re-assessment process (performing audit and completing corrective actions) should be completed before the expiration of the current certificate.

Following the expiration of the above mentioned period without the completion of the relative process, a reassessment of the quality system for certification renewal is no longer permitted. The client should, if he wishes, to follow again the process of the initial certification according to the terms set forth in sections 7 and 8 of this Regulation.

11. Certification Validity

The validity of the issued certificates and confirmations are:

Up to five (5) years for certificates of conformity related to the Directive 93/42/EEC and the Ministerial Decision ΔΥ8δ/Γ.Ρ.οικ.130648.

Up to three (3) years for confirmations related to the Ministerial Decision ΔΥ8/1348/04.

Up to three (3) years for certificates of conformity related to standards.

12. Use of Certificates and CE marking

A. General

The Certification Marks of EKAPTY is exclusive property of EKAPTY.

The Conformity Certificate and Certification Mark exclusively concern the client they have been granted to.

The Conformity Certificate and the Certification Mark of EKAPTY should be reproduced and published only in full and without any modification.

The client is committed to immediate pause of the use of the Certificate and Certification Mark when the validity period lapses or after a justifiable request of EKAPTY in accordance with the provisions of this Regulation.

B. Quality System Certificate

In any promotion of the certified Quality System, the client can use the granted by EKAPTY Certification Marks which are presented in **Appendix - A -**

The client has the right to use the Certification Mark in any promotion, in all documents, positions and advertising material provided that he respects the legislation.
The use of the Certification Mark on devices of the client and / or on the packaging thereof is expressly prohibited. Furthermore, it is prohibited to make any reference to the certification in a way that could be considered as the approval of the devices conformity. Given that the "product" of a laboratory is the results issued, it is prohibited for the certified laboratories to use the Certification Mark on the issued reports.
The use of Certificates and Certification Marks must be clearly associated with the brand name of the client and must be dedicated to their scope of application (organization - operations - sections to which it relates). The above mentioned particulars may appear translated in other languages beyond Greek.
The validity of the Certificate, and therefore the right to use the Certification Mark of EKAPTY, refer to each certificate and are subject to its specific requirements for conformity with standards and legislation and the present Regulation of EKAPTY.
For any other use which is not covered by the present Regulation, the client should contact the Certification Department of EKAPTY.

C. CE Marking

The CE Marking 0653 will be used exclusively on the devices that have been certified for the client.
The application and use of the CE Marking 0653 must comply with the requirements of the ΚΥΑ ΔΥ8δ/Γ.Π.οικ.130648.

13. Interruption of Certification

The client, if he wishes, has at any time the right to renounce the use of the Certificate and Certification Mark. In this case he has to notify in writing the requestto EKAPTY, to return the granted certificate(s) and immediately pause any use of the certificates and marks granted.

14. Rights of Certificates holders and CE marking

The holder of the Quality System Certificate of EKAPTY can use it for professional purposes, especially in cases of offers, agreements, confirmation of orders, for promotional purposes and to demonstrate the conformity of the company's quality system with the ministerial decision or standard in respect of which it has been certificated.

The holder of the CE marking must affix to the certified devices the labeling approval from EKAPTY and has the right to use it for professional purposes, particularly in cases of offers, agreements, confirmation of orders for promotional purposes and to demonstrate the conformity of his devices with the corresponding requirements.

15. Obligations of Certificate holders

The Certificate holder shall

- continuously implement the procedures provided by the approved quality system
- implement effectively within the stipulated time the appropriate corrective actions to waive the non-conformities and provide relevant information to EKAPTY
- declare that he holds and displays the Quality System Certificate of his company exclusively for the activities it has been certified for
- declare that he holds and display the CE Marking 0653 exclusively for the certified by EKAPTY medical devices of his company
- not use the Certification and not make any statements regarding the certification in a way that can be understood as misleading by EKAPTY
- pause within a maximum of one week any use, advertising and reference to the certification, if the certificate is withdrawn for any reason
- immediately return any certification documents to EKAPTY if the certificate granted is withdrawn for any reason
- immediately notify EKAPTY if the quality system of his company fails to meet further the requirements of the Ministerial Decision or the respective standards
- not involve changes to the applied quality system without written update of the Certification Department of EKAPTY and the corresponding written approval. If more than twenty days pass without a written response from EKAPTY, this is deemed as approval
- acknowledge the certificates granted by EKAPTY to other companies
- inform the auditors of EKAPTY accurately and in truthful way on all data relating to the company and to facilitate the assessment and surveillance procedures by taking appropriate organizational measures and by providing the auditors with the responsible personnel and related to the audit forms and documents and records of complaints and corrective actions taken in accordance with the requirements of the standards and / or legislation

- immediately inform EKAPTY in case of an adverse event over a patient or user of the devices
- immediately inform EKAPTY in case of recall of one or more devices
- respect the terms of this Regulation

16. EKAPTY's Obligations – Responsibilities

- EKAPTY has full responsibility for granting, maintaining, extending, suspending or withdrawing the certification.
- EKAPTY carries out assessments and audits in an objective, impartial and discreet way, in accordance with the requirements of the standards, legislation and relevant guidelines
- EKAPTY ensures the impartiality and competence of the partner organizations or individuals who are assigned to perform tests, audits or other technical activities.
- The staff and external collaborators of EKAPTY involved in assessment processes have the appropriate education, experience and expertise and operate within the context of the procedures, regulations and EKAPTY Code of Ethics.
- EKAPTY is responsible for the selection, training, assessment and supervision of auditors, audit planning and decision making regarding the conformity of the quality system with the applicable requirements.
- EKAPTY provides guidance on the audit teams and ensures the consistent way of dealing with the implementation of legal requirements and standards.
- EKAPTY notifies each time the auditee for the composition of the audit team and makes replacement of a member or members if justifiably requested.
- In case the client complains about the objectivity of the audit, EKAPTY performs a new audit at its own expense and with different composition of the audit team.
- EKAPTY informs the Competent Authority about all the certificates granted and any suspension or withdrawal of certificates, as provided by the legislation.
- EKAPTY certificates apply to each and every Member State of the European Union. EKAPTY is not responsible if third countries do not recognize or acknowledge partially the granted certificates.

- EKAPTY is not responsible in case of claims that are brought for liability due to damage caused by defective devices of the certified company.

17. Improper use of Certificates or CE Marking

In case of misuse of certificates and / or CE Marking the penalties provided by the relevant legislation apply.

18. Suspension – Withdrawal of Certification

EKAPTY may proceed to suspension and / or permanent withdrawal of the certificates issued. The decision to suspend or withdraw the certificates is made by the Certification Committee.

The following issues are some examples of withdrawal - suspension:

- Identification of serious deviations from the requirements of legislation or standards that may set a risk for the public health and security
- Denial of the client to accept surveillance audit
- Significant modifications to the applied quality system that are not updated to EKAPTY
- failure to waive non-conformities within the stipulated time
- Misleading use of certificate
- Misleading and / or false information from representatives of the client to the audit team during the audit
- Non-fulfillment of financial obligations of the client to EKAPTY regarding the certification process
- Bankruptcy of the Company
- Failure to meet the requirements of the present Regulation
- Client's request to cease the use of the certificates

A. Withdrawal

The withdrawal of the certification is communicated in writing to the client and the competent authorities within five days from receiving the decision. Also, after the determined time interval for an objection, EKAPTY discloses to the public the withdrawal by any appropriate means.

The company is removed from the list of the certified companies.

EKAPTY demands in writing from the company to return all granted certification documents and forms and specifically prohibits any use of the certificate or logo. In case of lack of response, EKAPTY will address the issue through the help of its Legal Counsel taking the necessary legal actions.

B. Suspension

The suspension of certificates is notified in writing by the EKAPTY to the client, and the requirements / corrective actions to waive it are laid down. The CompetentAuthority is also notified of the suspension.

Throughout the duration of the suspension the client is not allowed to make any use of the certificate and place on the market the devices marked as CE 0653. The suspension of the certificate is marked on the List of Certified Companies. As soon as the preset requirements are met the suspension is waived and the client is notified in writing by EKAPTY.

Where the measures taken are not considered satisfactory, EKAPTY may give a new deadline up to 30 days for the imposition of corrective actions before the final withdrawal of the Certificate.

If adequate corrective action is not implemented, the withdrawal of the Certificate becomes permanent and there apply those set forth in paragraph a of this chapter.

19. List of Certified Companies and Devices

The EKAPTY keeps an updated file of the certified organizations which includes the client's name, address, type of licenses, the validity period, the certification field and the name of its/ their device(s).

20. Objections

The concerned party may appeal against decisions of EKAPTY for certification issues (non-certification, suspension - withdrawal) within ten (10) working days from the notification of the decision.

The hearing of objections is performed by the Independent Certification Council, further to experts recomentation, if necessary.

The final decision shall be issued within one month from the date of the application and its implementation is mandatory. Until its adoption, the previous decision applies.The applicant is informed of the decision within five days from its receipt.

Any expenses for the examination of the appeal by EKAPTY are charged to the objector where appropriate.

21. Financial Terms

The costs of all stages for obtaining and maintaining certificates are described in detail in the Certification Price List.

The client is informed of the total cost of certification, all costs included, with a comprehensive bid submitted by the Marketing Department.

Client's failure to respect the financial terms is a cause for termination of the cooperation and withdrawal of the granted certificates.

22. Revision of the present Regulation

The present Certification Regulation may be revised in part or in its entirety, following a decision of the Board of Directors of EKAPTY.

Any revisions are communicated in writing to the clients who have been granted a Certificate, specifying the deadlines for adapting to the new requirements. In case of disagreement with the above mentioned changes, the client may in writing request the termination of the certification.

ANNEX A


ΟΡΘΗ ΔΙΑΝΟΜΗ ΙΑΤΡΟΤΕΧΝΟΛΟΓΙΚΩΝ ΠΡΟΙΟΝΤΩΝ
ΔΥ8/1348/2004
ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ
ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ
ΣΤΗΝ ΥΓΕΙΑ Α.Ε.


MEDICAL DEVICES DISTRIBUTION
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NATIONAL EVALUATION CENTER
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IN HEALTH S.A.


ΟΡΓΑΝΙΣΜΟΣ ΜΕ ΣΥΣΤΗΜΑ ΠΟΙΟΤΗΤΑΣ
EN ISO
9001
ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ
ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ
ΣΤΗΝ ΥΓΕΙΑ Α.Ε.


ORGANIZATION WITH QUALITY MANAGEMENT SYSTEM
EN ISO
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ΟΡΓΑΝΙΣΜΟΣ ΜΕ ΣΥΣΤΗΜΑ ΠΟΙΟΤΗΤΑΣ
EN ISO
13485
ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ
ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ
ΣΤΗΝ ΥΓΕΙΑ Α.Ε.


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