

Document No: FR.23.02 Issue Date: 15.12.2015 Revision No: 08 Revision Date: 28.04.2021

#### 1. DEFINITIONS

- 1.1 "NOTICE": Notice Certification, Inspection and Audit Services,
- 1.2 "Auditor": Personnel performing conformity assessment on behalf of NOTICE on a permanent or contractual basis,
- 1.3 "Agreement": FR.23.01 Certification Proposal/Agreement document mutually signed by NOTICE & customer,
- 1.4 "Logos": sign and symbols defined in NOTICE Certificate and Use of Logo Procedure (PR.21) and described later in this document
- 1.5 NOTICE and Customer will be referred to as "Parties" hereinafter.
- 1.6 "Services": Services include application evaluation, document examination, site audit, reporting (certification, surveillance, recertification and follow-up audits in case necessary), and certification provided by NOTICE for Certification purpose.

### 2. SERVICES AND AUDITORS

- 2.1 Customer assigns NOTICE for providing services by signing the agreement. This agreement is considered complete together with attachments and correspondence if any; Certification Rules & General Terms is an integral part.
- 2.2 NOTICE will apply necessary technical skills and sufficient attention while providing certification services.
- 2.3 NOTICE does not take or accept any additional responsibility or duties regarding any not defined in this document.
- 2.4 NOTICE may employ third parties for Services. This situation does not make the third party responsible. To maintain impartiality, it is guaranteed that there is not any conflict of interest or any other conflict between these third parties and the customer, and the third parties have not provided the customer with consultancy services.
- 2.5 To maintain impartiality while providing services, auditors shall not have any conflict of interest or any other conflict with the customer. Auditors cannot give consultancy services to the customer.
- 2.6 Auditors will stay away from any type of pressure (including commercial issues) which will affect the services to be provided.
- 2.7 Selection procedures related to Auditors' expertise and duties are guaranteed by their training and experience. NOTICE owns required facilities and infrastructure for providing services in reasonable time.
- 2.8 In case a certain part of the services is subcontracted, necessary information is communicated to the customer. NOTICE remains responsible for the subcontracted service.
- 2.9 The customer is responsible for providing auditors' protection and necessary personal protective equipment.

## 3. CUSTOMER'S LIABILITIES

- 3.1 The customer shall give NOTICE documents related to manufacturing, service places, facilities and activities covered by NOTICE's service scope. All changes occurring in this regard shall be communicated to NOTICE in written.
- 3.2 The customer sends NOTICE the related documentation and give them access for document examination.
- 3.3 The customer allows auditors to enter facilities, access system and records as agreed in different stages of services.
- 3.4 The customer will not conceal from NOTICE any information related to the services.
- 3.5 In the framework of relevant standard and regulations, the customer is obliged to comply with any kind of written or verbal information and instruction taken from NOTICE for operation of the management system, product conformity assessment, inspection and testing services.
- 3.6 The customer whose management system or the product related to the management system is certified shall assign one of the personnel for ensuring the implementation and continuity of the established system, provide auditors' access to all the required areas in working hours, guarantee the provision of all national legislations or special requirements apart from the management system standard.

3.7 Observers or guides can accompany NOTICE in the inspections, audits or unplanned visits carried out in the customer's site. Observer may be there to observe a member of audit/ inspection team, ma be an authorized person of customer, accreditation body or the related ministry. Guides are individuals accompanying the audit team for assistance. Any member of the audit team can be assigned as guide. Guide's responsibilities can be making communications, arranging meetings, organizing site audit, having site safety regulations applied, witnessing the audit on behalf of the customer or providing the information requested by the auditor.

The customer and auditors are informed of participation of guide and observers prior the audit and customer's approval are taken. Guides and observers cannot interfere the audit.

- 3.8 The customer, is obliged to declare any kind of verbal or written information to NOTICE personnel, TÜRKAK representatives or ministry authorities regarding audit or inspection activities while necessary.
- 3.9 The customer shall inform NOTICE within 10 days of changes in management system or the certified product related to the management system, the company's system or products in the certificate scope after certification and changes affecting system's structure (address(es), scope, number of workers, number of branches, address of branch(es), etc.)
- 3.10 The customer shall maintain all the records related to the activities carried out by NOTICE (agreement, report, QMS records, etc.) for the certificate validity period as well as the product in the certificate scope for its shelf life.
- 3.11 The customer shall make all the necessary documents for the application available to NOTICE before the inspection and audit.
- 3.12 NOTICE can carry out inspections or audits in order to evaluate the effect of the applied changes on the system or product.

The customer shall apply the changes occurred to NOTICE inspection and certification system (standard procedure or regulations) in the defined period.

- 3.13 In the scope of the certificate the customer shall record the complaints received from its customers or third parties and shall inform NOTICE of the complaints during the audit. The customer shall inform NOTICE and the Competent Authority of any adverse event and the performed actions in that regard.
- 3.14 The customer shall comply with and follow the update status of documents such as Certificate and Use of Logo Procedure, Certification procedure, Certification regulations and General Condition, etc. Issued at <a href="https://www.notice.com.tr">www.notice.com.tr</a>, related directives, standards and all the other legislations.
- 3.15 The customer is required to pay the fees defined in the service agreement or the fees of specific audits of related standards or directives or follow-up audits.
- 3.16 Upon suspension and withdrawal of the certificate, the customer is required to stop the use of certificate and any advertisement material referring to the certificate and shall sends the certificate back to NOTICE.
- 3.17 The customer shall comply with national legislation, regulations and standards. Companies willing to receive product conformity certificate, are required to comply with all requirements defined in the directive and CE marking requirements.
- 3.18 After the certification audits, the customer shall inform NOTICE of any changes occurring to internal and external processes.
- 3.19 Customers file the complaints as described in PR.24 Objections and Compliant Evaluation Procedure issued at <a href="https://www.notice.com.tr">www.notice.com.tr</a> and in case does not accept the Objection Committee's decision, can apply to the related legal authority (Turkish Accreditation Agency or Ministry of Health). In case NOTICE exceeds the time for resolving the complaint, the customer can apply to the related legal authority in the same way. The customer can object to the decision made by NOTICE within one month.
- 3.20 The customer shall fulfill the essential requirements or other statuary requirements stipulated in 93/42/EEC Medical Device Directive and national legislations for product(s) design and production and the conformity assessment requirements according to 93/42/EEC Medical Device Directive.



Document No: FR.23.02 Issue Date: 15.12.2015 Revision No: 08 Revision Date: 28.04.2021

- 3.21 The customer can use the certificate for the address and scope written on the certificate. In case of violation, the customer accepts the consequences.
- 3.22 In case of providing others with copies of certification documents (certificate, report, etc.) the customer shall replicate the documents as whole.
- 3.23 The customer accepts and that NOTICE will not provide any consultancy services in the scope of conformity assessment and for the issues related to this scope will not request so.
- 3.24 By way of derogation from Article 5 of this Regulation, a device which has a certificate that was issued in accordance with Directive 93/42/EEC and that is valid, may be placed on the market or put into service until the application Regulation (EU) 2017/475 it continues to comply with either of those Directives, and provided there are no significant changes in the design and intended purpose. However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives.
- 3.25 After Eudamed is fully functional; manufacturers, importers and representatives have to sign in to Eudamed.

#### 4. NOTICE'S RESPONSIBILITIES

- 4.1 NOTICE and all its personnel will keep confidential any kind of verbal and written information received from the companies in relation with certification and inspection activities, this information is shared only upon request of TÜRKAK and Ministry of Health. For other third parties, the information will be shared only on court decision. In this case, the customer will be certainly informed.
- 4.2 NOTICE, retains its personnel under the control of Impartiality and Confidentiality as a requirement of impartiality and confidentiality and the accredited standards.
- 4.3 For the risks in the scope of certification and inspection which may cause loss or harm, NOTICE owns "Professional Liability Insurance" in which limits and scope are defined. NOTICE has taken the necessary precautions for all the situations not covered by insurance and provides assurance to all customers regarding such conditions. In case the certificates are not identified by third parties, no responsibility lies with NOTICE.
- 4.4 NOTICE will inform its certified customers of significant changes in certification and inspection system (standard procedures, regulations) in the shortest time and announces the need to make the necessary modificairons. Website, email, etc can be used for this purpose.
- 4.5 NOTICE has the right to make changes in procedures prepared related to services and the pricings. However, conditions before the change remain valid and the date of the document change is considered as base. NOTICE shall announce document changes to certified and applicant companies through website, fax or email. In case the occurred changes will cause a situation in favor of the previous customers, it will be applied in a way to cover them as well.
- 4.6 NOTICE is responsible for issuing and updating certified, suspended and withdrawn customers in the website.
- 4.7 In case NOTICE decides to terminate its accreditation activities or related authorities decide so, the companies certified by NOTICE will be left to the supervision of a certification body accredited by an IAF member.
- 4.8 In case NOTICE decides to terminate its notified body activities or related authorities decide so, NOTICE will transfer the company's file to a Notified Body defined by the company. In this situation, the requirements of the other notified body are liable and NOTICE does not have any right to interfere the requirements.
- 4.9 Other than the above-mentioned situations, NOTICE undertakes to comply with standards, directives, TÜRKAK guidelines, IAF guidelines and EU commission documents for certification and inspections.
- 4.10 NOTICE takes no responsibility or liability for cancellation of the project in case site audits cannot be performed due to travel restrictions or national entry bans by the destination country.

### 5. CERTIFICATION ACTIVITIES

- **5.1 Application**; Certification applications are received through **FR.07.01 Application Form.** The customer fills in this form thoroughly and sends it back together with the documents requested documents in the form.
- **5.2 Application evaluation**; NOTICE evaluates the applications received from customers and the decision on accepting or rejecting the application will be communicated to the customer in written

In case the application is accepted, Certification proposal/agreement is prepared for management system and/or product conformity certification. Audit activities according to related standard and directives will be planned considering audit man/day duration.

- 5.3 **Certification Audit;** Certification audit will be carried out in the form of Stage 1 & Stage 2 audits.
- 5.4 **Audit Findings;** Following the audits carried out by NOTICE personnel, the findings are communicated to the customer through audit report. In case of negative findings (not fulfillment of standard and directive requirements for the customer's service/service scope), the findings are recorded in FR.08.01 Nonconformity and Follow-up Report and the customer is informed.

Negative findings are defined as follows:

**Major Nonconformities:** nonconformities which affect the ability of management system to achieve the desired result. Nonconformities can be classified as major in the following situations:

There is a significant doubt about process control effectiveness or fulfilling service requirements,

There is a series of systematic nonconformities on the same subject or requirement series of failures.

**Minor nonconformities:** nonconformities which do not affect the ability of management system to achieve the desired result.

The time required for closing nonconformities is defined together with the customer. This time cannot exceed 90 working days. Otherwise, the customer's application will be cancelled. The process will be started over form application stage depending on the customer's decision. Nonconformities identified in relation with quality management system and/or technical documentation shall be properly closed in order the be able to pass to the next step in the certification process.

In case the time for closing nonconformities has exceeded 90 working days but the customer has declared reasonable justification in written, Lead auditor, Medical device in charge and accreditation and notification in charge will evaluate customer's declaration. IN case the customer if customer is found right, additional time not exceeding 6 months from the audit date. If the justification is not accepted, the process is terminated.

Due to the EU 2017/745 Medical Device Regulation transition process, all non-conformities must be closed until 10 May 2021 before the validity date of the 93/42 / EC Medical Device Directive.

- 5.5 **Certification decision**; The decision made by NOTICE personnel after the rectification off nonconformities is not the final decision. Certification decision is taken by certification committee. In case the certificate is decided to be granted, the justifications are communicated to the customer in written. After the assessments, before taking the decision on whether or not to grant the certificate, additional document or audit may be requested.
- 5.6 **Certificate Issue**; The customer's certificate will be issued according to the information in audit report, after NOTICE certification committee evaluates the customers' quality management system requirements and/or product technical documentation and/or product technical documentation, implementation of relevant standards and/or fulfillment of directive's requirements. Certificates are granted in the form of 1 Turkish and 1 English original copy. Requested additional copies will be charged (1 copy 100€ + KDV). The certificate will be issued on <a href="www.notice.com.tr">www.notice.com.tr</a> and will be accessible after the related fields are filled in the site. The information published in this area is public and is not confidential, it contains the following information.
- Organization Name
- Information on city, country of the organization addresses within the scope of certification
- Certificate scope



Document No: FR.23.02 Issue Date: 15.12.2015 Revision No: 08 Revision Date: 28.04.2021

- Certificate status (Active, Cancelled, Suspended)
- Information on the assessment standard /regulation

The organization may wish to have the above information limited due to security reasons or to the fact that it is confidential information. However, this limitation must be communicated to NOTICE by the applicant organization in written, stating the reasons and signed by the authorized person prior to the publication of the certificate. NOTICE will not accept liability for material or non-material damages if notification is not made.

5.7 **Follow-up Audits**; In case the major nonconformities identified during the audits carried out in customer's premises in the scope of certification agreement (stage 2 audit, surveillance audit, recertification, transfer, unannounced, short notice, change audits) need to checked on site, follow-up audits are carried out. Follow-up audits are performed on the dates agreed with the customer. Audit plan is sent to the customer prior to the audit.

Follow-up audit for certification audits are carried out within 90 days after stage 2 audit.

For other audits, the process is proceeded in the same way. Follow-up audit date is defined according to the time given to other audits.

5.8 **Surveillance Audits;** Surveillance audits are carried out by NOTICE to continue the QMS and product conformity certificate of certified customers. First surveillance audit will be carried out within 12 months from the certification decision date, surveillances of the following years will be performed once in a calendar year within one calendar year of that date. In case the audit cannot be carried out due to reasons from customer's side, the certificate will be suspended. Audit frequency can be increased according to the nature of nonconformities found in the customer's premises during the audit. In case of increase, the customer will be charged for the surveillance audit according to the signed surveillance agreement.

The period for closing the identified nonconformities (regardless of the type: major or minor) in the surveillance audit is 60 working days. The company is required to define the corrective actions to remove nonconformities in 15 days and submits them to NOTICE through FR.08.10 Nonconformity and Follow-up Report. If decision on necessity of follow-up audit is taken during the audit, the process explained in 5.7 will be followed. In case the customer fails to close the nonconformities with proper corrective actions in the defined period (if additional time has not been requested), the certificate will be suspended.

Note: In case during the audit, the customer requests additional time for closing the nonconformities, the request is received in written including the justifications. The request sent by the customer is evaluated by NOTICE accreditation and notification in charge, Medical device department in charge and the relevant lead auditor. Accepting or rejecting the additional time depends on this evaluation.

If the customer properly closes the nonconformities identified during the surveillance audit in due time or incase no nonconformities are found during the audit, in accordance with the decision of certification committee, the certificate will remain valid for the period mentioned on the certificate. Certification committee may take different decision from the audit team's, may request for additional document of additional audit.

NOTE: Due to the EU 2017/745 Medical Device Regulation transition process, the expiry date of the EC Certificate of Conformity provided by NOTICE under the 93/42 / EC Medical Device Directive is May 26, 2024. EC Certificate of Compliance issued by NOTICE after this date will be invalid pursuant to article 120 of EU 2017/745 Medical Device Regulation.

Within the scope of the 93/42/AT Medical Device Directive, surveillance audits and unannounced audits will be carried out by us until May 27, 2024.

### 5.9 Recertification Audits;

Certificate renewal audits are those conducted to recertify companies before the certificate validity period (system certificate 3 years, product certificates 5 years or until) is due.

At least 6 months before the certificate validity period is over, NOTICE contacts The Company and requests reply. The audit shall be planned within the certificate's validity period. Otherwise, the certificate expires at the end of the validity period.

NOTICE will review the results of the previous audit, notifications related to The Company and the auditor's remarks before contacting The Company for recertification audit. In case the recertification application is decided to be rejected as a result of evaluations, The Company will be informed in written.

In case The Company requests recertification audit before the certificate expiry, the decision will be communicated to The Company.

Before recertification audit, recertification agreement will be made with the customer according to PR:23 Audit Price Determination Procedure. Recertification process is conducted according to PR.09 Surveillance and other audits procedure.

#### 5.10 Change Audits;

Changes Originating from Customer; Audits carried out to control changes such as customer's title, scope of activities, address and branches, etc., If the customer's official status (address, title, etc.) has changed, service agreement will be changed before the audit.

Change requests are received from customers through FR.08.15 Change Notification to NB/CB Form in written, NOTICE decides on document examination or site audit and comments on the form. In scope change or address change audits, besides document examination, site audit will be carried out and audit report is prepared. In change audits not needing site audits, objective evidence is gathered and decision can be made without NOTICE certification committee meeting. (e.g.: in case of change in alley, street, number, etc. by local government). For other changes final decision will be made by NOTICE certification committee. Certification committee may request additional certificate or additional audit at the end of the evaluation.

In case of certificate change, the validity period of the company's existing certificate is not changed. Revision status and date will be written on the certificate.

Changes Originated from NOTICE: NOTICE informs customers of changes in certification requirements and related processes (Scope reduction, standard/ directive change, changes applied to its own system, etc.) through email and also issues them at <a href="https://www.notice.com.tr">www.notice.com.tr</a>.

According to the change status, planning in charge will contact the customer and plans the related audit. In case the customer does not accept the audit, the process for transferring the customer to another notified body defined by the customer will be started. The certificates remain valid in the period defined for transition.

By way of derogation from Article 5 of this Regulation, a device which has a certificate that was issued in accordance with Directive 93/42/EEC and that is valid, may be placed on the market or put into service until the applicaition Regulation (EU) 2017/475 it continues to comply with either of those Directives, and provided there are no significant changes in the design and intended purpose.

For instance, administrative changes of organisations are considered in principle as nonsignificant. This includes changes of the manufacturer's name, address or legal form (legal entity remains) or changes of the authorised representative.

Furthermore, all changes not having an impact on the design or the intended purpose of the device can be regarded as not significant in the meaning of Regulation (EU) 2017/475 Article 120(3). This is the case for example of relocation or addition of new manufacturing sites, including when it affects subcontractors or suppliers, or of certain changes of the quality management system, provided that the conditions for which the conformity assessment certification was granted are maintained. Nevertheless, such changes continue to be subject to the agreed notification procedure identified in the first paragraph of the current section. The manufacturer should always remain responsible for providing evidence that all the abovementioned changes do indeed neither affect the design nor the intended purpose.

On the other hand, when the change is likely to affect the design or the intended purpose of the device, the significance of such a change must be assessed on a case-by-case basis

To facilitate a harmonised judgement of the significance of changes flowcharts (see Annex of MDCG 2020-3 Guidance) have been developed



Document No: FR.23.02 Issue Date: 15.12.2015 Revision No: 08 Revision Date: 28.04.2021

5.11 **Short Notice Audits**; In case of complaints with objective evidence, NOTICE can contact The Company and decides to perform an extraordinary audit. In these types of audits, The Company will be informed a short while (max. 1 day) before the audit not to provide the possibility of changing the current conditions.

to the possible extent. NOTICE assigns an audit team different from the one who carried out the previous audit. The team shall definitely be able to comment on the complaint. In case the customer does not accept the audit, its certificate will be suspended and the customer is accordingly informed in written. Besides, other than the situation explained above, in case of negative perceptions or if it deems necessary to NOTICE or TURKAK, unplanned visits can be carried out. The audit is recorded through the audit report. In case nonconformities are detected during the audit, the surveillance audit process will be followed.

Upon termination of the audit, if essential requirements are proved not to be fulfilled, the certificate will be suspended or withdrawn according to the severity of nonconformities. Suspension/withdrawal decision will be communicated to the company in written together with the justification.

5.12 **Unannounced Site Audits**; The purpose of announced audits is to remove any doubts regarding the safety of the product in the conformity assessment scope.

The audit is conducted by verification of an appropriate amount sample of recently produced certified as well as site control (product, lot, group).

Unannounced audits are certailnely carried out at least once in 3 years.

Unannounced site audits are carried out once in 3 years without sending any prior notice to The Company.

NOTICE appoints personnel with the assigned product code for the audits. Audit duration will be defined as at least 2 man/day.

If the manufacturer has subcontracted all its critical processes and the review is to be carried out on the documents only, this duration will be reduced to half man/day, but additional time will be added for critical contractor visit. Critical processes are within the scope of unannounced audits. If additional time is required for the audit, the reasons for the addition are defined and documented in the audit report.

Audit frequency and duration is defined in the following table:

	Min. Frequency for unannounced audits	Classification			
			lla	IIb	
ı	Normal Conditions	3 years	3 years	3 years	2
	In case of recurring nonconformities for the device	2 years	2 years	1 year	1
ı	In case of suspicion on nonconformities related to the device	2 years	2 years	1 year	1

In case the customer does not accept unannounced audit and/or impedes the assessment team from auditing, the minutes are recorded by assessment team. The company's certificate will be suspended by NOTICE. Suspension decision will be communicated to the company.

In case at the end of the audit, essential requirements are proved not to be fulfilled, the certificate will be suspended or withdrawn considering the nonconformity magnitude. Suspension/ withdrawal decision together with the reasons are communicated to the customer in written.

**5.13 Certificate suspension and withdrawal;** Suspending certificate's entire scope or a part thereof is an intermediate precaution before withdrawing the certificate. Certificate suspension period cannot exceed 6 months.

NOTICE retains the right to suspend certificates in the following conditions:

- The Company enters significant changes or pauses the activities (on customer's request)
- The existence of nonconformities which impairs The Company's management system
- Surveillance audits could not be planned
- Corrective actions for rectifying the nonconformities have not been finished within 60 working days

- The customer resists adapting its management system to changes in certification system or NOTICE procedures.
- Incorrect representation of certification process, misuse or abuse of logo, certificate and related documents
- The customer acts contrary to management system principles and undermines certification process integrity
- The customer acts contrary to NOTICE's service agreement and the regulations mentioned in this document
- The Customer does not fulfill its financial liabilities towards NOTICE
- Major and minor nonconformities are identified after the Certification audit and have not been closed
- The customer cannot maintain compliance to the legal requirements essential for the certificate
- The customer has been involved in accidents or events (e.g.: events threatening public health) as a result of violating the principles of the base standard for the certificate and not being able to maintain compliance to it.
- Upon customer's request
- In case of sanctions placed on the company's origin country on the related sector (Health, medical device) by United Nations, European Commission and the United States

In case customer seriously fails to fulfill certification requirements, partially or entirely, NOTICE reduces the customer's certificate scope so that the unfulfilled requirements part will be excluded.

In all the situations not needing technical evaluation like not accepting surveillance audit, not fulfilling financial liabilities not timely closing of nonconformities certificate will be suspended directly without need to certification decision committee meeting. In all the other cases suspension decision is taken by certification committee.

NOTICE informs the customer of suspension of the certificate together with the justification in written on the its letterhead paper.

Once the reasons for suspension are successfully eliminated or in the case of certifiates suspended upon customer's request, after the reated \*activity for lifting the suspension, depending on the suspension reason is carried out, the customer is informed of the continuation of the certificate and takes back all its right on that. Throughout the suspension period, the customer can keep the certificate, however, cannot benefit the rights.

\* If the suspension process is initiated upon the customer's request, correct understanding of the suspension reasons is important to start processes after customer's request to lift the suspension. The premoval of the suspension reasons declared by the customer shall be

verified before the suspension is revoked. For instance, in case the certificate is suspended upon customer's request due to the address change and later the customer requests the suspension to be revoked, address change audit shall be conducted and once the fulfillment of conditions have been verified, the suspension shall be lifted. Another issue is the possibility of suspension requests due to financial reasons. When a request for lifting, the suspension is received after the financial problems are resolved, the certification cycle status is controlled. If the surveillance audit has just been carried out in the company before suspension request is placed, and suspension revocation is requested before the next surveillance/certification audit, a no change declaration regarding the company's address and certificate scope is taken and in case it is verified, necessary procedure (address change, scope extension, etc.) is followed and the certificate suspension is lifted until the next audit date.

In cas the decision to suspend the certificate partially or as a whole, the status of the certificate is marked as suspended in <a href="https://www.notice.om.tr">www.notice.om.tr</a>. Once the suspension conditions are removed the certificate status is marked as active in the web ite.

In case the cuatomer cannot eliminate the suspension reasons in 4 months, the certificate will be withdrawn.

NOTICE has the right to withdraw the customer's certificate in case the above-mentioned situations occur. Before withdrawal, certificates are suspended. Certificates may be directly withdrawn according to the magnitude of nonconformities (situations in which the customer



Document No: FR.23.02 Issue Date: 15.12.2015 Revision No: 08 Revision Date: 28.04.2021

violates the principles of the certificate's base standard and directive) and in the following situations:

- The customer goes bankrupt or ceases the activities
- The customer does not use the certificate for the address and scope defined on the certificate
- The customer presents false and misleading information during the audit
- The audits prove that the customer's management system is totally ineligible
- The customer tampers with the certificate and the annexes

In case the cuatomer cannot eliminate the suspension reasons in 4 months, the certificate will be withdrawn.

Other than these situations, customers themselves can request the certificate withdrawal. Withdrawal request is taken in written. The request is evaluated by NOTICE and the customer is informed following its approval.

NOTICE informs customers in written of certificate cancellation together with the justifications. The customer sends the original certificate(s) to NOTICE upon withdrawal.

Following informing the customer of the certificate withdrawal, the customer immediately stops the use of NOTICE and accreditation body (TURKAK)'s logo, CE mark and other phrases representing its certification. This is applied to advertisement, logos and marking used in the plants as well.

The certificate status is changed to cancelled on  $\underline{\text{www.notice.com.tr}}$  web site. Customer who

decides to retrieve the withdrawn certificate shall start over the application process. NOTICE informs customers of certificate suspension, scope reduction and withdrawal in written. NOTICE has the right to publicly release the necessary information about certificate suspension, scope reduction and withdrawal. Customers' can make objection to certificate suspension, scope reduction and withdrawal. NOTICE notifies the accreditation body and Competent Authorities of suspended and withdrawn certificates and those with reduced scope. Besides, suspended, withdrawn and certificates with reduced scope are announced at <a href="https://www.notice.com.tr">www.notice.com.tr</a>.

5.14 **Certificate and Use of Logo;** Customer is entitled to use NOTICE's logos according to PR.21Certificate and Use of Logo Procedure, relevant IAF and EA regulations upon successful termination of audit activities and certification result.

According to the agreement made with the customer, the customer entitled to use the logo of the accreditation body from which NOTICE has got its authority, can use NOTICE's logo together with the accreditation body logo provided that the customer complies with accreditation body rules. Once the agreement is terminated, the customer is obliged to stop the use of the logos.

### 6. PAYMENTS

Fees defined in the agreement are paid to one of the NOTICE's accounts according to the conditions defined in "Fees" clause of the agreement. The transfer costs incurred during payment and any reductions arising from the similar matters are not accepted. All the travel, accommodation costs, etc. of the audit team are also borne by the company. For products incorporating medicinal substances, the expenses related to the competent authority's evaluaton is to be borne by the Customer.

## 7. CANCELLATION OF THE AGREEMENT

This document and the agreement become invalid in case the parties are informed in written at least one month in advance. NOTICE has the right to cancel the agreements if the information provided by the customer during application is proved to be misleading and wrong or the logos are proved to be used improperly. If the customer requests cancellation of the agreement, he will be charged for the services provided up to that point.

### 8. COMPLAINTS

The customer has the right to file a complaint to NOTICE for any kind of unresolved problem related to the received services from NOTICE. Customer's complaints are evaluated according to PR.24 Complaints & Objections Evaluation Procedure.

## 9. DOCUMENTS

The updated versions of all the procedures and instructions referred to in this document are accessible at <a href="https://www.notice.com.tr">www.notice.com.tr</a>.