**TABLE OF CONTENTS**

## 1. SERVICE

UDEM is an organization that evaluates the compliance of management systems with international standards. .

## 2. APPLICATION

## 3. Applications for certification service . is made with the FRM.81 ISO 13485 Application Form . . on the UDEM website (www.udem.com.tr)APPLICATION ACCEPTANCE/REJECTION CONDITIONS

The customer is obliged to fill in the **FRM.81 ISO 13485 Application Form** completely and to send the official documents specified in **FRM.16.M ISO 13485 Offer and Agreement** to UDEM. Incomplete or incorrect information detected may result in rejection of the application. UDEM may reject the application due to the fact that the applied scope is not within the scope of UDEM's accreditation and/or there is no conformity assessment personnel or the appropriate audit team cannot be formed.

## 4. AUDIT PROCESS

The customer can get information about the certification process any time from UDEM. The customer must ensure that the management system for certification application fully complies with the relevant standard or requirements and operates the management system. The customer must notify UDEM within 15 days of any change in its conditions (system, personnel, organization, equipment, etc.) that may invalidate the relevant certificate.

UDEM conducts surveillance audits at appropriate intervals, no longer than a 12-month period, to ensure the continued validity of the management system. This period may vary depending on audit results or organizational structure. For nonconformities to be identified in the audits, the customer must create a corrective action plan within 15 days and submit the corrective action evidence UDEM within 3 months.

UDEM notifies the customer about the audit plan and audit team for the planned audits at least 2 days before the audit. The customer reserves the right to object to the audit date and audit team in writing.

The customer is obliged to allow UDEM authorized personnel to access its work areas, operations, services, management system, all records and personnel during normal working hours during the audit period and to demonstrate at least one of the production processes in practice.

The audit program includes an initial certification audit consisting of stages 1 and 2, surveillance audits in years 1 and 2, and a recertification audit in year 3 before certificate expires. For detailed information on the audit process, please contact the System Certification Unit. . The audit process is carried out by sampling. UDEM is not responsible, directly or indirectly, for any loss, damage or harm that may arise from the customer's management system's full non-compliance standards or other requirements.

UDEM prepares a report after its audits and presents its findings in 3 ways as stated below;

**Major Non-Nonformity:** The following situations are reasons for major non-comformity;

- No documentation of any clause of the standard or no examples of implementation for any clause,
- The existence of significant doubt about effective process control or conformity of products/services to specified specifications,
- The presence of a large number of minor nonconformities, indicating that there may be a systematic deficiency and thus constituting a major nonconformity,
- The customer has a significant doubt about the ability of the management system to achieve its intended results

Major non-conformities may require a follow-up audit.

**Minor Non-conformity:** Although any article of the standard is documented and application examples are available; non-conformity detected in the event that any application that affects the achievement of the intended results of the management system is found to be missing is included in this class.

**Observation:** Although any clause of the standard is documented and fully implemented, findings for the efficiency and effectiveness of the implementation based on the auditor's sectoral experience are included in this class. If not implemented until the next audit, it is reported as minor non-conformity.

All fees related to the audit shall be paid to the account numbers specified in the customer agreement. . Failure to make payments may result in suspension or even withdrawal of certification.

When the UDEM audit team is in the customer's work areas, the customer is responsible for their health and safety. Before entering the customer site, brief the audit team on health, safety and emergency evacuation procedures and the potential health and safety hazards they may encounter during their visit, and provide them with appropriate safety equipment and clothing.

## 5. CERTIFICATES

Certificates issued by UDEM are controlled documents that belong to UDEM and must be returned to UDEM in the event of withdrawal or revocation of the certificate. Unless withdrawn, cancelled and maintained with satisfactory performance, issued certificates are valid for a certain period of time. Certificates cannot be transferred automatically in case of change of organization owner, structure or address. Requests for transfer must be in writing and transfer applications will be reviewed on a case-by-case basis for the UDEM's authorized personnel to decide how to proceed.

## 6. REFUSAL OF CERTIFICATION

As a result of the management system audit, the audit report is reviewed by the System Certification Manager and the certification committee. As a result of the review, if there is a negative situation in the audit report that will affect the certification, UDEM may decide to reject the certification.

## 7. LOGO, MARK and CERTIFICATE USAGE

In cases where the right to use the UDEM logo is granted, the use of the logo is subject to specified restrictions. No rights can be claimed beyond the documented scope. The use of the logo, trademark, document and other rights must not be misused to imply certification of the product. Changes in scope are possible, but may require a site audit. The use of logos, trademarks and documents is defined in **TLM.02 System Logo, Mart and Certificate Usage Instruction**. This instruction is made publicly available on the UDEM website (www.udem.com.tr)

## 8. CONFIDENTIALITY AND ACCESS TO INFORMATION

All information and documents related to the ustomer and are kept securely by UDEM personnel. The content and scope of certificate will remain confidential when you apply to UDEM for an audit, but will be published on the UDEM website after the certification decision has been made. At the same time, UDEM has the right to publish changes in the status of the certificate. Confidential information is not disclosed without the customer's consent. If such information is requested to be disclosed by legal authorities, UDEM will notify the customer.

UDEM requires its conformity assessment personnel, and other personnel to comply with the principle of confidentiality in order to protect all kinds of information about the customer and , and to declare that they do not have any interest relations that may arise from their participation in the audit process.

UDEM is not responsible for any loss, damage and harm caused directly or indirectly by the person who does not comply with the confidentiality agreement from its employees. UDEM is not liable for any confidentiality information that is known to its personnel prior to the application for certification, or that becomes publicly known through no fault of , or that is disclosed with customer'consent.

## 9. SUSPENSION, WITHDRAWAL, CANCELLATION OR REDUCTION IN SCOPE PROCESS

### 9.1. Suspension Process

UDEM suspends the customer's certification in the following cases:

**1.** Continuous and serious failure of the customer's certified management system to meet the certification requirements,
**2.** The customer does not allow surveillance or recertification audits to be carried out at the required frequency, does not fulfill its financial obligations, without providing reasons other than force majeure,
**3.** The sustomer voluntarily requests a temporary suspension,
**4.** In cases of major non-conformities requiring follow-up audits in surveillance audits; situations that threaten product safety and user health (sterilization process insecurity, use of suspicious raw materials, etc.),
**5.** Failure to complete corrective and preventive actions within the periods specified in the observation and non-conformity form submitted to the customer organization after the surveillance audits,
**6.** Non-conformities are not corrected in the follow-up audit or new non-conformities occur.
**7.** At least 1 of the production processes cannot be demonstrated practically in field audits.

The customer is sent this document (FRM.13-1 ISO 13485 System Certification Requirements) which defines the rights they have during the suspension process. The status of the customer whose certification is suspended is made publicly available on the UDEM website.

If new non-conformities are found in the customer whose certification is suspended as a result of surveillance audits, the certification is withdrawn.

During the suspension period, the customer's certification is temporarily invalid. For this reason, the customer must refrain from any activity that will advertise its certification during this period. In the event of suspension or withdrawal of certification, the organization must stop the use of logos, trademarks and documents in accordance with the **TLM.02 System Logo, Mark and Certificate Usage Instruction** available on the website.

The maximum period of suspension is 6 months. Depending on the criticality of the situation, this period may be less than 6 months. At the end of 6 months, certificates that are not suspended are cancelled. However, at the end of the suspension period (6 months), if the customer has reasonable grounds that will not affect product safety, the certification committee may decide to extend the suspension period for a maximum of 12 months in total, once only. These grounds are as follows:

- Infrastructural improvement works,
- Supplier-linked processes,
- No payment has been made for the relevant conformity assessment process.

If a follow-up audit is required for two consecutive years and the reason for follow-up is due to the same substances; the relevant certificate may be suspended with the approval of the committee. In case of suspension, unannounced audits may be conducted by UDEM.

### 9.2. Reinstatement Process

In the event that the assessments made for corrective actions and / or, if necessary, the follow-up audit result is positive or if the audit that could not be performed, which is the reason for suspension, is planned, the decision to suspend the certificate is taken by the certification committee based on the audit report prepared. The customer's certificate can only be suspended with the decision of the committee.

### 9.3. Withdrawal and Cancellation Process

If the customer whose certification is suspended does not remedy the non-conformities during the suspension period or does not comply with the certification conditions in any way, the certification will be withdrawn. Withdrawal of certification means that the customer's certification is canceled by UDEM and the contract is terminated. The customer whose certification is withdrawn must reapply to receive services from UDEM. The status of the customer whose certification is withdrawn is made publicly available on the UDEM website.

Certification is withdrawn in the following cases:

- The customer does not agree to the terms of the suspension,
- Failure of the customer to remove the grounds for suspension,
- The customer fails to provide confirmation for a follow-up audit at the end of the suspension period,
- Failure to close the nonconformities identified follow-up inspectionscarried out forthe removal of the suspension within the prescribed periods,
- Misleading and unfair use of the document by the customer in areas other than the product or service specified in the document,
- The customer cannot be found at the facility address specified in the document,
- Falsification of the document by the customer,
- In case of closure of any of the sites or branches owned by multi-site customers, the certification will be withdrawn if the customer neglects to inform UDEM.
- The head office or any of the sites fulfills the requirements for the maintenance of the certificate the certification is canceled in its entirety.

Certification is cancelled in the following cases:

- Customer demand,
- The customer's bankruptcy or termination of its activity within the scope of the certificate,
- Change of legal entity of the customer,
- Failure of the customer to request document renewal.
- Failure to fulfill administrative and financial obligations under the contract.

If the customer has not applied for a follow-up audit within 6 months after the certificate has been suspended, additional time may be granted or the certificate may be withdrawn by the decision of the Certification Committee. In case of withdrawal/cancellation of the certificate, the organization must fulfill the following obligations:

- Suspension of the use of the UDEM logo, accreditation mark and certificate,
- Waiver of any rights under the withdrawn/cancelled certificate,
- Payment of outstanding certificate or audit fees.

Within **1 month** following the withdrawal of the certificate, the organization must remove the UDEM logo from all correspondence and promotional materials. If a contrary situation is reported to UDEM;

- Informs the relevant accreditation body and other certification bodies,
- It announces in various media that the organization is using the document inappropriately,

in violation of the rules of the contract,

- Therefore, it applies for legal remedies for the compensation of material and moral damages.

Special circumstances that may lead to suspension and withdrawal are set out below:

- In cases of major non-conformities requiring follow-up audits in surveillance audits; 6.3 and 6.4 and in cases that threaten product safety and user health (sterilization process insecurity, suspicious raw material use, etc.), the audit team must submit the audit reports and related nonconformities to the committee for evaluation within 7 days. On the same day, if the committee decides that the situation is critical, it may decide to suspend (Critical situation: It is for the purpose of deciding to stop the production of the product on the grounds of threatening patient health).
- Major non-conformities and other major/minor non-conformities identified in the surveillance audit and requiring follow-up should be closed as of the audit date and provided that the follow-up audit is carried out within a maximum of 2 months, and a decision to suspend or withdraw should be taken by the committee within 1 month following these two months. Follow-up audit should be planned to be completed within 2 months as of the audit date and the follow-up audit plan should be shared with the customer organization.
- If there are grounds for suspension again in the first audit carried out for a suspended company, a cancellation decision is taken.
- If a follow-up audit is required for two consecutive years.

In case of a follow-up recommendation from the audit team after the follow-up audit;

a. If the reason for follow-up is due to the same substances; it is suspended with the approval of the committee. In case of suspension, an unannounced audit is carried out.
b. If it is due to different articles, it may be decided to reduce the period of surveillance audits from 1 year to 6 months with the decision of the committee.

### 9.4. Scope Reduction Process

If the customer demonstrates a persistent or serious failure to meet the certification requirements for a portion of the certification scope, UDEM will reduce the customer's certification scope to exclude the portion that does not meet the requirements. Once the scope of certification is reduced, the customer must replace all advertising materials. However, the scope of certification can be reduced at the customer's own request. The customer whose scope of certification is reduced is asked for its certificate and a new certificae is issued and delivered to him/her. The need to reduce the scope may arise if the customer does not comply with the conditions that the customer must comply with during the certification process or during audits. In general, no audit is carried out to narrow the scope. The status of the certificate of the customer whose scope is reduced is published on the UDEM website.

### 9.5. Scope Expantion Process

Customers can apply to UDEM to expand the scope of their certified management systems with a petition to be written on their letterhead. The petition received from the customer is forwarded to the Certification Manager. Certification Manager examines the request and determines whether the expantion can be made or not. .

- If the scope to be expanded is outside the technical areas owned by our organization, the request is rejected.
- If the scope to be expanded is in the same technical area as the existing scope of the customer and the product realization in the existing validated processes is deemed sufficient by the lead auditor

conducting the office review, the recommendation of the lead auditor can be evaluated by the certification committee. If the decision of the certification committee is positive, the certificate issuance process is carried out for the situations that will affect the certificate.

- If the scope to be expanded is in a different technical area, an audit is required to determine whether the customer is eligible for this scope. Scope expantion and surveillance audits can be combined with the approval of the requester. After the audit, the customer file is submitted to the certification committee after the nonconformities, if any, are eliminated. If the decision of the certification committee is positive, the certificate issuance process is carried out for the situations that will affect the certificate.

## 10. COMPLAINTS and OBJECTIONS

The customer may file an objection or complaint with UDEM against any audit finding or decision on the basis of work or omission. Such complaints must be made in writing to UDEM. The evaluations obtained as a result of the objection will be notified to you in writing in detail. Complaints/appeals shall be submitted to UDEM **FRM.38 Complaint and Appeal Evaluation Form**, which is made publicly available on the UDEM website. . For complaints about the customer's management system, UDEM may conduct an investigation at the customer's site . UDEM will not decide on any complaint of financial loss. All details of the grievance and appeal process are described in **PD.09 Procedure for Handling Complaint and Appeals** available on the website.

## 11. RECERTIFICATION PROCESS

Recertification audit is performed for the recertification of management systems of customers whose 3-year certification cycle has expired, if they so request. The planning responsible contacts the customer to be recertified by 2 months before the audits are due. The recertification decision must be made before the end of the 3-year certification period. Exceeding this period is only possible due to force majeure. Force majeure events are natural disasters, epidemic, revolution, war, general strike and economic crisis. When force majeure occurs, the maximum period to be granted to the customer is 3 months, if the audit cannot be carried out at the end of the 3-month period, the validity of the document expires.

The recertification audit is planned and implemented in the same way as the initial certification process. The objective of the recertification audit is to confirm that the management system as a whole continues to be appropriate, effective and relevant to the scope of certification and its applicability. To this end, the recertification audit includes a field audit to address the following items

- The effectiveness of the management system in its entirety and its sustainable relevance and applicability to the scope of certification in the light of internal and external changes,
- Demonstrated commitment to sustain the effectiveness and improvement of the management system to enhance overall performance,
- The extent to which the operation of the certified management system contributes to the realization of the organization's policy and objectives.

A Stage 1 audit is not mandatory in the recertification audit but is required in the following cases

- Management system,
- Customer,
- Significant changes in the scope in which the management system operates (such as changes in legislation, changes in regulatory documents, etc.).

For this, the customer must notify our organization of such changes. In addition, the following documents are requested from the customer for a preliminary examination:

- New or revised system documents of the organization
- Signature circular of the authorized signatory
- Copy of the Trade Registry Gazette
- Certificate of Activity

After the audit is reviewed by the certification committee of the customer file (audit reports, audit plans, customer's quality management system documentation, etc.) and a new certificate is issued after the certification committee decides to recertify.

In the new certificate, issue date of the first certificate is also indicated. The validity period of this new certificate is 3 years from the day of the recertification decision.

## 12. TRANSFER AUDITS

The transfer process applies only to applications from certification bodies accredited by accreditation bodies covered by the IAF MLA agreement. If other organizations apply for transfer, they are treated as new customers and their certification process is started from the initial certification phase.

If the the company's previous certificate has not expired and the surveillance audit date has not yet arrived, certificate is transferred and the audit is carried out when the surveillance audit date arrives.

For the transfer, the organization's system documents and the audit records of the previous certification body are requested and examined. If the company is suitable for transfer, a contract is made and the surveillance audit process is initiated.

Transfer applications of organizations that are suspended or in danger of suspension are not accepted. Nonconformities detected in the system documents of the organization applying for transfer are notified to the relevant organization in writing. The nonconformities must be closed by the current certification body before the transfer audit. If some doubts arise as a result of these examinations, the applicant organization is evaluated as a new customer or an audit focusing on the areas identified as problematic can be carried out.

If the previous certification body has terminated its business relationship, its accreditation has expired, suspended or withdrawn, the certification processes are started from the first certification stage.

After the above-mentioned conditions are completed and the transfer application is accepted, the surveillance audit process is carried out. The certification committee takes the certification decision regarding the transfer audits to complete the certification process.

## 13. LIMITATION OF LIABILITY

It is agreed that UDEM's liability to its customers is strictly limited to . Your contract with UDEM, which is only liable for the agreed fee, is fundamental and UDEM will not be liable for any loss or damage that may occur.

## 14. OTHER CONDITIONS

The requirements of the conformity assessment process may be revised over time. Significant changes will be notified in writing. The standard terms of reference shall be governed and interpreted in accordance with the laws of TURKEY.

## 15. RELATED DOCUMENTS

- FRM.81 ISO 13485 Application Form
- FRM.16.M ISO 13485 Offer and Contract
- FRM.38 Complaint and Appeal Evaluation Form
- PD.09 Procedure for Handling Complaint and Appeal Evaluation
- TLM.02 System Logo, Mark and Certifciate Usage Instruction

| Prepared by | Controlled By | Approved by |
|---|---|---|
| ISO 13485 System Certification Manager | Management Representative | General Manager |