



## CERTIFICATION REQUIREMENTS FOR CERTIFICATION SERVICES

**Service:** UDEM certifies management system according to “criteria” published by another institution. For instance; International standards. All audits will be carried out with our independence authority.

**Application:** Applications are sent with Application Form. You can reach application form from our web site on **ONLINE APPLICATION** link.

**Audit Process:** You have authority to receive information about certification process. This will be provided by us. You can be sure that our management system and procedure are in coherence with Standard or criteria for certificates which are going to be issued. Please inform us when there is a change on your conditions (systems, staff, organization, equipment, etc) if they are subjected to affect validity of your certificate.

To be sure the continuity of validity of your systems, we'll apply surveillance audits to be sure the conformity of your system in every 12 months. Regular surveillance audits which are nearly similar to initial audit or an whole reassessment. Any non-conformity detected during your audits should be closed in an agreed time between us and in accordance with the requirements.

UDEM will declare requirements to carry out audits, date and time of these actions will be discussed.

Entrance allowance should be provided to UDEM authorized personnel in normal working hours, in your working areas, processes, services to apply audit and review action with your staff and for your procedures, records include corrective actions and complaints.

Audit process is a sampling process. UDEM is not directly responsible for any loss or damage because of 100 % compliance or non-compliance of your management system to standards and other criteria.

UDEM will be classified non-conformances to Standard under 3 type of non-conformities:

1. **MAJOR:** When there is no documentation to one of the Standard items or there is no application samples for any item. If there is significant doubt as to the effectiveness of process control or compliance with specified characteristics of products and services; If there are numerous minor incompatibilities that show that there may be a systematic deficiency with a condition or subject, and thus constitute a major nonconformity. Also, any serious suspicion to the capability of customer to realize objected results of management system. Major non-conformity can necessitate follow-up audit. The report can not be closed until compliances of the non-conformity. The planning period of the corrective and preventive action is 15 days and closing period is approximately 3 months.
2. **MINOR:** If there is a lackness on the application of documented item of a Standard and existing of application samples, the non-conformity will be classified as minor. Minor non-conformity does not need follow-up audit. It can be based on documents. The planning period of the corrective and preventive action is 15 days and closing period is approximately 3 months.
- 1- **RECOMMENDATION:** Definitions of auditors based on their sectoral experiences to improve the efficiency of applications when Standard items are documented and applications are carried out completely. **RECOMMENDATION** can be applied before the next audit and efficiency of working periods can be improved. Corrective or preventive action may not be opened.

Necessary information can be received from contact information part on the web site if information demanded related to classifications of non-conformities and about all other audit processes.

It will be agreed that your payment of all fees and costs related to the audit to our authorized personnel in UDEM. Any trouble about payments can be caused suspension or withdrawal of the certification.

It will be agreed about health and safety of UDEM personnel when they are in your working area. It will also be agreed to give them a brief information about health, safety, emergency conditions, excavation procedure during their visit. Also, you'll be responsible to provide safety equipments to UDEM authorized personnel and auditors.

**Certificates:** Conformity certificates published by UDEM are controlled documents provided by us and they should be returned us in the case of withdrawal or abandon of the certificate. Published certificates are valid for a period of time unless they are withdrawn or abandoned and as soon as the satisfactory performance is maintained. Your certification will be withdrawn if there is a significant or repeating mistake. Certificates are not transferred, when



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the place of the owner of the organization, structure is changed. Demand should be in written for transfers and it will be examined based on the case to decide the action of our UDEM responsible.

**Rejected of Certification:** As a result of the audit of the management system, the Audit Report is audited by the Director of Documentation and the committee. In the event that there is an adverse event that will affect the documentation in the audit report as a result of review, the UDEM may decide to reject the certification.

**Logo, mark and usage of certificate:** Using of logo is restricted when the using of logo right has been given. Any right has not been claimed except the certified scope. There can be changes on the scope, however it normally need audit and you should contract with UDEM authorized personel o n this subject.

**Confidentialiy and Access to Information:** All kinds of information and manuals, documents or records will be kept in safety conditions. Context of your certifate and scope will be kept confidential, however it will be published after guaranteed. At the same time, we have authority to suspension/ withdrawal/ renewal of the certificate. Confidential information will not be declared without your permission. If these kind of information asked by legal authorities, we will inform you about sharing the information.

Before started to work with us our auditors and other personel committed to maintain compliance with the principle of confidentiality may arise from their participation in the audit process to declare an interest if interest require. We are nor responsible for any loss or damage caused directly or indirectly because of our personnel, managers, auditors who does not meet confidentiality agreement.

We are not responsible for privacy information which shared by your self or publicly known or the information of which our personnel, auditors and manager already knew before certification application.

**Suspension and withdrawing:** You can demand suspension or withdrawing of your certificate is you think that your system is not suitable for system requirements. Recertification may need a full time audit.

UDEM can suspend or withdraw your certificate, if your system is not commit Standard requirements or criteria, when the fees and costs are not paid, the Convention on the standard requirements of the job is reporting an opinion or a situation that may shadow the reputation of the certification process.

As a result of your audit, if a major non-conformity detected which neded to apply a follow up audit, the time needed for the declaration of objective evidence of implementation of the actions to **UDEM** and the realization of the follow-up audit is again 3 months at the latest. If it is noticed during the follow-up audit that the nonconformities have not been removed or new nonconformities have occurred or if the CPAs which have been applied for the minor nonconformity are not found sufficient and effective by the lead auditor, application of the client is suspended and a follow-up audit is performed again 3 months later. In case the result of the follow-up audit is positive, the prepared audit report is presented to the Documentation Committee by the Documentation Director and the document of the company can be downloaded by the committee decision.If it is noticed that nonconformities are not removed at this follow-up audit yet certification is withdrawn and you should apply again.

When your management system certification or certificate suspended or withdrawn, usage of logo & certificate of *UDEM Adriatic D.o.o* and name of *Adriatic D.o.o.* is prohibited.

**Complaints and appeals:** You can complaint and appeal to any finding during an audit or declaration of the decision to UDEM for work or negligence. These kind of complaints should be declared to UDEM in written. Complaints about you from 3rd parties will be transmitted to you. UDEM can do examination to decide how your system traced. UDEM will not take decision about any financial loss complaint.

**Scope reducing:** If it is realized that the client persistently or seriously fails to meet the requirements certification for some parts of the certification scope, UDEM reduces the client's certification scope excluding those parts which do not meet the requirements. Client has to change its all advertising materials when the scope of certification is reduced. Moreover, certification scope can be reduced upon request of client's own. Certificate of the client is requested back from the client of whom the scope of certification is reduced on condition that they will be sent the new certificate arranged according to the new scope. Need for scope reducing may arise during the audits or when the client does not obey the rules during certification process. In general audit is not realized for scope reducing. Status of the client is also announced through web site of UDEM



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**Scope Extension Audit Process:** UDEM clients can apply to UDEM for scope extension in their management system by a petition which they will write on letterheads. The client writes the EA or NACE codes for which they would like to get extension in the petition. The application which sent by the client back is forwarded to the Certification Manager. Certification Manager determines whether the extension will be performed or not after examining the demand. He transfers the relevant decision to the Certification Printing Unit.

- The demand is rejected if the scope to be extended is out of scopes of UDEM.
- If the scope that will be extended has the same NACE code with the client's existing scope (up to three digits), the scope is changed with the approval of the lead auditor that has performed the audit without performing a new audit. However, new scope is checked at the following next surveillance audit.
- The scope to be extended is in different EA or even NACE code, audit is required to determine whether the client is compatible with this scope or not. To prevent the client from paying for excessive amounts, they are suggested that audit can be made in the frame of the first following surveillance audit. If the client accepts, while the first further surveillance audit is planned, the demand/ petition is saved in the Client's folder to ensure the inclusion of scope extension to the plan. If the client requires that the extension of scope is performed immediately, they may not accept the combination of audit with the surveillance audit. In this case, a new audit is planned by applying surveillance audit process. The certificate is required from the client whose scope is changed by extension and a new certificate is arranged and sent to the client.

**Recertification Audit Process:** The re-certification audit is conducted to re-certify management systems at the request of the end-users of the 3-year certification cycle. The customer who is to be re-certified will be contacted by sending the FRM.52-Re-Documentation Information Form 2 months ago. For ISO 13485 FRM.144 Surveillance/Yeniden Documentation Information Form is sent to the company and asked for sign. The re-certification decision should be made at the end of the 3-year certification process. It is possible to overcome this problem only by force majeure. Examples of attacks include fire, earthquake, flood, and the work of the customer. When a force majeure occurs, the customer is given a 3-month period, and the inspection is canceled if the 3-month period ends.

This audit is planned and implemented and completed as it was during the initial certification process. The purpose of the re-certification audit is, as a whole, the confirmation of the relevance and effectiveness of the management system and its relation to the scope of the certification and its continued applicability. To this aim, the re-certification audit should include a field audit to address the following:

- d) In the light of internal and external changes, the effectiveness of the management system in its entirety and the scope of documentation and sustainable interest and applicability,
- e) the commitment to maintain the effectiveness and improvement of the management system to improve overall performance,
- f) The contribution of the operation of the documented management system to the realization of the organization's policy and objectives.

Stage 1 audit is not mandatory in re-certification audit and is needed in the following situations:

- In the management system,
- Customer,
- Significant changes in the scope of the management system (such as legislative changes, changes in regulatory documents, etc.).

To do so, the customer must notify our organization of any such changes. In addition, the following documents are required for a preliminary examination:

- New or revised system documentation (Handbooks and Procedures)
- Signature circulars of the authorized signatory
- Copy of Trade Registry Gazette
- Operating certificate

After the audit report and the TGG, the Documentation Committee will issue a new document upon re-certification decision.

A new document will be issued by the documenting committee upon the decision of re-certification. The date of the first document editing of the new document is also specified. The validity period of this new document is 3 years from the date of the re-certification decision.



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**Transfer Audits:** Transfer is only applicable for applications from certification bodies accredited by accreditation bodies under the IAF MLA agreement. If other certification bodies apply for transfer, they will be treated as new customers and certification processes will be initiated at the initial documentation stage.

If the previous document of the firm has not expired and the surveillance audit date has not yet arrived, the document is transferred and carried out when the surveillance audit is received.

For the transfer, the system documents of the organization and audit records that the previous certification body has made are requested and examined. If the company is suitable for the transfer, the surveillance audit process is started by contracting.

Transfer applications of organizations that are suspended or suspended are not accepted. Any nonconformities found in the system documents of the applicant organization shall be notified to the relevant organization in writing. The resulting incompatibilities must be closed by the existing certification body before the transfer audit. In the event of a doubt as a result of these reviews, the applicant may be considered as a new customer or an audit may be carried out which focuses on the areas identified as problematic.

If the previous certification body has terminated its business relationship and accreditation is terminated and withdrawn at the suspended location, the certification processes are initiated at the initial certification stage.

Following the completion of the above conditions and acceptance of the transfer application, the surveillance audit process is carried out. In order to complete the certification period, the Documentation Committee shall take the decision of certification concerning transfer inspections.

**Limitation of Liability:** It will be agreed that our responsibility to you will be limited certainly.

UDEM Just over the agreed fee basis and are responsible for your agreement with UDEM will be responsible for loss or damage that may occur.

**Other Conditions:** Standard requirements of the work can be revised in time. Significant changes will be declared in writtten. Standard requirements of the work will be managed and commented in accordance with laws in Croatia.