



CERTIFICATION REQUIREMENTS FOR CERTIFICATION SERVICES

Service: UDEM ADRIATIC D.O.O. certifies the management system according to “criteria” published by another institution. For example; International standards. All audits are carried out by our independent authorized personnel.

Application: Applications are sent with the Application Form. You can access the application form from our website on the **ONLINE APPLICATION** link.

Terms for Acceptance/Rejection of Application: The customer is obliged to send official documents specified in the contract to UDEM Adriatic d.o.o. The customer should completely fill out the UDEM Adriatic d.o.o. application form. If UDEM ADRIATIC d.o.o. finds insufficient or incorrect information, this may cause UDEM ADRIATIC d.o.o. to reject the customer's application. UDEM ADRIATIC d.o.o. may reject the application if the reported scope is not included in the scope of UDEM Adriatic d.o.o.'s accreditation and/or if an appropriate audit team cannot be appointed, for the reason that there are no auditors/technical experts in the specified scope.

Audit Process: You are authorized to receive information about the certification procedure. The company UDEM Adriatic d.o.o. will provide you with all information about the certification process. You can be sure that our management system and our procedures comply with the requirements of the standard and/or criteria related to the certificates we will issue. When there is any change in your conditions (systems, personnel, organization, equipment) that could make your certificate invalid, you must inform us as soon as possible.

To ensure that the validity of the certificate for your systems is extended and that the 12 months is not exceeded, we will conduct surveillance audits at a suitable time interval. This period can be shortened by the decision of our authorized personnel. Regular surveillance audits are almost similar to initial certification or recertification. Any non-conformity detected during the audit must be closed in accordance with the requirements and in the time interval that we will determine.

UDEM ADRIATIC d.o.o. will inform you in advance about everything necessary for conducting the audit, and the date and time for these activities will be agreed upon in agreement with you.

Authorized personnel of UDEM ADRIATIC d.o.o. will be granted permission to enter your business premises during normal working hours, and access to your work premises, procedures, services, and records containing information about personnel, corrective and preventive actions and complaints received, in order to conduct an audit and assessment.

The audit program includes a certification audit consisting of phases 1 and 2, surveillance audits in the 1st and 2nd year and a recertification audit in the 3rd year before the certificate expires. For detailed information regarding the audit procedure, please contact UDEM Adriatic d.o.o.'s System Certification Manager. The audit procedure is carried out by a sampling process. UDEM Adriatic d.o.o. is not responsible for any type of business loss or damage that is directly related to the conformity or non-conformity of your quality management system with standards or other criteria.



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UDEM ADRIATIC d.o.o. will make a classification of non-conformities in accordance with the requirements of the standard into 3 classes:

1. **MAJOR:** In the event that any article of the standard is not documented or there are no examples for the application of any article of the standard, the determined non-conformity enters this class. If there is a significant doubt concerning the implementation of effective process control or the conformity of services and products against the specified characteristics; If many minor non-conformities are found which indicate that there may be a systemic deficiency related to the requirements and which together constitute one major non-conformity. Also, if there is doubt about the customer's ability to realize the targeted results of the management system. Major non-conformity may require a follow-up audit. The audit report cannot be concluded without determining whether the non-conformity has been closed. The time for planning the corrective and preventive actions that should be implemented is 15 days, and the time for closing non-conformities is a maximum of 3 months.
2. **MINOR:** If there is a deficiency in the application of the documented item of the standard and the absence of an example of its application, the non-conformity will be classified as minor. Despite the documentation of an article of the norm and the existence of an example of application, if there is any deficiency in application that may affect the ability of the management system to achieve the targeted results, the determined non-conformity falls into this class. A minor non-conformity does not require a follow-up audit. It can be evaluated by reviewing the submitted documentation. The time for planning the corrective and preventive activities that should be implemented is 15 days, and the time for closing non-conformities is a maximum of 3 months.
3. **RECOMMENDATION:** Despite the documentation of any article of the standard and the complete fulfillment of its application, the clarifications that the auditor will provide for a more effective application, relying on his sector experiences, enter this class. RECOMMENDATION is applied until the next audit, and the efficiency of business processes can be increased. Corrective and preventive actions cannot be open.

If you need more detailed information about the classification of non-conformities and other audit procedures, you can get them through any of the communication channels listed in the Contact Information section of our website.

The payment of all costs and fees to UDEM Adriatic d.o.o. for the audit service performed by our authorized personnel will be contracted. Difficulties in collection or the impossibility of collection of the mentioned fees and costs could result in the suspension or withdrawal of the certificate.

It will be agreed about the health and safety of UDEM ADRIATIC D.O.O. personnel when they are in your working area. It will also be agreed to give them brief information about health, safety, emergency conditions, and evacuation procedures during their visit. Also, you'll be responsible for providing safety equipment to UDEM ADRIATIC D.O.O. authorized personnel and auditors.



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Certificates: Certificates of conformity issued by UDEM Adriatic d.o.o. are official documents owned by UDEM Adriatic d.o.o. and in case of withdrawal or abandonment of the certificate, they must be returned to UDEM Adriatic d.o.o. The issued certificate is valid for a certain period until the certificate is withdrawn or canceled or continued with appropriate activities (surveillance audit, recertification). In case of a cardinal error or one that is repeated frequently, your certificate will be withdrawn. In the event of a change in the owner of the organization, the structure of the organization or the location, the certificates cannot be automatically transferred. Requests for certificate transfer must be expressed in writing and in some cases, UDEM ADRIATIC D.O.O. will conduct an evaluation so that the responsible person of UDEM Adriatic d.o.o. can decide on the necessary activities.

Refusal of certification: As a result of the management system audit, the System Certification Manager and the Certification Committee review the audit reports. In the event that, based on the review, some negative situation is found in the audit report that could affect the certification, UDEM ADRIATIC D.O.O. may decide to refuse certification.

Use of the logo, trademark and certificate: In cases where the right to use our certification logo has been granted, its use is limited. No right to use the certification logo can be exercised outside the scope in which the certification was carried out. The use of the certification logo and certificate for systems should not be carried out in a wrong way that could refer to product certification. Changes in the scope of certification are possible, but in this case it is necessary to carry out the usual audit and UDEM ADRIATIC D.O.O. authorized personnel must decide on the matter.

Confidentiality and access to information: UDEM Adriatic d.o.o.'s authorized personnel will not disclose confidential information regarding your company, manuals, documentation or records. The content and scope of your certificate will remain confidential until a certification decision is made. At the same time, we have the right to suspend/withdraw/renew your certificate. Confidential information will not be disclosed without your permission. If legal authorities request certain information, we will notify you.

When starting employment, we will ask our auditors and other employees to respect the principle of confidentiality when keeping any type of information related to you, and to make a statement that there is no conflict of interest that could arise due to participation in the audit process.

We are not responsible for any loss or damage caused directly or indirectly due to our personnel, management, or auditors not complying with the confidentiality agreement.

We are not responsible for confidential information that you share yourself or that is publicly known or information that our personnel, auditors and management already knew before applying for certification.

Suspension and withdrawal: If you believe that your system is not in compliance, you can request a temporary suspension or withdrawal of your certificate. Re-renewal of the certificate will require a complete audit.

If your system does not comply with the requirements of the standard or its criteria, that the fee and costs have not been paid, that we have received information about how your business does not comply with the requirements of the standard, or if it is believed that this is a situation that



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will violate the basic certification procedure, UDEM ADRIATIC D.O.O. may suspend or withdraw the certificate.

When a major non-conformity that requires a follow-up audit is determined as a result of your audit, the time required to declare objective evidence to UDEM Adriatic d.o.o. regarding the implementation of activities and for the realization of a follow-up audit is again a maximum of 3 months. If it is noticed in the follow-up audit that non-conformities have not been closed, or that new or minor non-conformities have appeared, or if the lead auditor has assessed the corrective and preventive actions that were carried out as insufficient and ineffective, the customer's application is withdrawn, and a follow-up audit is performed again 3 months later. If the result of the follow-up audit is positive, the System Certification Manager presents the prepared audit reports to the certification committee, and the suspension of the customer's certificate can only be terminated by the committee's decision. If it is determined that non-conformities have not been removed even in the follow-up audit, the certification is withdrawn and you need to apply again.

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

Complaints and appeals: You can file a complaint with UDEM Adriatic due to any auditor's omission, finding or decision during the audit. This type of complaint must be sent to UDEM ADRIATIC D.O.O. in writing. You will be informed about the resolution of your complaint in more detail also in writing. Third-party complaints concerning you will certainly be transmitted to you. UDEM ADRIATIC D.O.O. can examine to decide how to monitor your management system. UDEM ADRIATIC D.O.O. will not make decisions on any complaint related to financial loss.

Scope reducing: If it is noticed that the customer shows a constant or serious failure in realizing the certification requirements for part of the certification scope, UDEM ADRIATIC D.O.O. reduces the customer's certification scope, in such a way as to exclude the part that does not meet the requirements. The customer has to change all advertising materials when the scope of certification is reduced. Likewise, the certification scope can be reduced at the customer's request. A certificate is requested from the customer whose certification scope is being reduced, and a new certificate is prepared, which is then forwarded to him. If the customer does not comply with the conditions that must be complied with in the certification process or during the audit, there may be a need to reduce the scope. In general, no audit is performed for scope reduction. The status of the customer whose scope is reduced is also published on UDEM Adriatic d.o.o.'s website.

Scope extension audit process: UDEM Adriatic d.o.o.'s customers can apply for extension the scope of certified management systems through a request written on an official letter (memorandum). The customer communicates in the request in which NACE and EA codes he wants to extend. The customer's request is forwarded to the System Certification Manager. The System Certification Manager reviews the request and communicates whether a scope extension can be implemented. He forwards his decision in this regard to the department for issuing certificates.

- If the scope that should be extended is outside the scope of UDEM Adriatic, the request for extension is rejected.



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- If the scope to be extended has the same NACE code with the existing scope of the customer (up to three digits), the scope is changed with the approval of the lead auditor who conducted the audit without conducting a new audit. However, the new scope is checked in the next surveillance audit.
- If the scope to be extended is in another EA or even another NACE code, an audit is required to determine whether the customer is compatible with this scope or not. To prevent the customer from paying excessive amounts, it is suggested that the audit be performed as part of the first subsequent surveillance audit. If the customer accepts, while the first subsequent surveillance audit is planned, the request is saved in the customer's folder to ensure that the scope extension is included in the plan. If the customer requires the scope extension to be carried out immediately, it may not accept the combination of an audit with a surveillance audit. In this case, a new audit is planned using the surveillance audit process. A certificate is requested from the customer whose scope is changed by the extension and a new certificate is prepared and sent to the customer.

Recertification Audit Process: A recertification audit is conducted to re-certify the management systems in case customers whose 3-year certification cycle has come to an end wish to do so. The FRM.17 Annual Audit Information Form is sent to the customer to whom the recertification audit should be conducted, 2 months before the actual audit. FRM.144 Information form for surveillance/recertification audit and FRM.144-1 ISO 13485 Information form for surveillance/recertification audit are sent to the customer, and the customer is asked to fill them out. The decision on recertification should be made before the end of the 3-year certification cycle. Postponement of this period is only possible due to force majeure. The group of force majeure includes events such as earthquakes, floods, fires, storms, revolutions, wars, general strikes and economic crises. When force majeure events occur, the maximum period given to the customer is 3 months, and if the audit is not carried out after those 3 months, it is canceled.

This audit is planned, carried out and completed in the same way as in the initial certification procedure. The overall goal of the recertification audit is to confirm the continuity of compliance of the management system, its efficiency, connection with the certification scope and its applicability. For this purpose, the recertification audit should include an on-site audit to ensure 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:

- Changes in the management system,
- Changes related to the 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:



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- New or revised system documentation (Manuals and Procedures)
- List of authorized signatories
- Copy of Trade Registry Gazette
- Operating certificate

After preparing the audit report and closing non-conformities, the new certificate is prepared by the certification committee in accordance with the recertification decision.

The date of issue of the first certificate is also defined in the new certificate. The validity period of that new certificate is again 3 years from the day when the decision on recertification was made.

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 certification stage.

If the previous certificate of the customer is still valid and the surveillance audit date has not come yet, the certificate is transferred and the surveillance audit is realized in time.

For transfer, by making a contract with the company accepting the offer, system documents of the company and records of audit performed by the former certification body are requested and examined. If the company is suitable for the transfer, the surveillance audit process is started by contracting.

Applications of companies suspended or under threat of suspension cannot be accepted. Nonconformities detected in the system documents of the organizations applying for transfer are declared to the related company in written form. Major non-conformities shall be closed by the current certification body before the transfer audit.

If there are any doubts as a result of these examinations, the applicant company is treated as the new customer or a pre-transfer review may be performed focusing on the areas that the company is determined to be 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.

After the completion of the requirements above and acceptance of the transfer application, the surveillance audit process is carried out. To complete the certification process, the Certification Committee shall decide on certification concerning transfer audits.

Limitation of Liability: It will be agreed that our liability to you will be limited. Loss or damage that may occur based on your contract with UDEM Adriatic d.o.o. will be covered up to the agreed professional liability insurance fee.

Other Conditions: The requirements of the standards related to the performance of our activities may be revised over time. Important changes will be communicated to you in writing. The requirements of the standards for the performance of activities will be implemented and interpreted under Croatian laws.