



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.

This Application: covers the product certification procedure and the quality management system applied in the manufacturing process of the product to be certified by the UDEM and accordingly the services and contracted services requested by the customer. The application form shall be signed with the manufacturer or the authorized representative within the scope of MDR 2017/745/EU.

Note: Within the scope of MDR 2017/745/EU, the manufacturer shall deliver the following documents to UDEM with the application form:

-The quality management system documentation

-Technical File,

Fees and financial conditions : Fees charged for specific conformity assessment activities and any other financial conditions relating to product certification are defined in UDTLM.17 Charging Instruction which is publicly available at www.udemadriatic.com.

Contract : The contract between UDEM and the customer concludes with the written notification that the customer has accepted the conformity assessment requirements after the approval of offer. The contract shall be signed directly between the manufacturer and the UDEM within the scope of MDR 2017/745/EU.

The following documents together with the Contract Cover Letter are demanded from customer:

- ❖ Technical File,
- ❖ Quality Management System documents of the organization (Handbooks, Procedures),
- ❖ Promotion documents if available (leaflets, catalogs, demo CDs etc.),
- ❖ List of authorized signatures belonging to the authority signing the contract,
- ❖ Copy of Trade Registry Gazette,
- ❖ Certificate of Activity,
- ❖ Tax Board
- ❖ Bank receipt or receipt of payment indicating the deposit of certification fee.

Note: In particular, the customer shall submit technical files and system documents to UDEM in English and Turkish from the above mentioned documents regarding conformity assessments. Except these documents, other documents can be accepted in English, Turkish, Croatian languages. All correspondence with the client after the contract is signed will be in English, Turkish or Croatian. If the documents are delivered on a different language than these languages, the customer is requested to translate them into one of these languages.

The conformity assessment (product certification) and quality assurance system for the product is applied according to Machinery Directive 2006/42 / EC, Machinery safety and relevant regulation NN 28/11, EC Type Examination Annex IX, Article 11 (3) (B) and (4) (a).



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Certification shall be carried out according to Annex IX of the 2006/42 / EC Machinery Safety Regulations for the following equipment / machinery:

- 9. Presses, including press-brakes, for the cold working of metals, with manual loading and/or unloading, whose movable working parts may have a travel exceeding 6 mm and a speed exceeding 30 mm/s (EN 692: 2009 (EN ISO 16092-1:2018) EN 693: 2012 (EN ISO 16092-3:2018) EN 12622: 2014, EN 13736: 2009);
- 10. Injection or compression plastics-moulding machinery with manual loading or unloading. (EN 201: 2010);
- 11. Injection or compression rubber-moulding machinery with manual loading or unloading. (EN 201: 2010);
- 13. Manually loaded trucks for the collection of household refuse incorporating a compression mechanism (EN 1501-1: 2015);
- 16. Vehicle servicing lifts .(EN 1493: 2010);
- 17. Devices for the lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than three metres. (EN 280: 2015, EN 1808: 2015, BS EN1495: 2009 / Ispr.2012, EN 12159: 2013,EN 14043:2014,EN 81-41:2010, EN 81-40:2008).

Accepting and refusing of application: The customer is responsible for providing the legal documents defined the contract to UDEM. The application form of UDEM has to be fully completed by the customer. UDEM has right to refuse application forms with missing and/or wrong information. UDEM has also right to refuse the application if the scope of application is not exist in the accreditation scope of UDEM and/or UDEM does not have appropriate audit team for the related application.

Audit Process: You have authority to receive informaiton about certification process. This will be provided by us. You can be sure that our management system and procedure are in coherenfe 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 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 nitial 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 declared requirements to carry out audits, date and time of these actions will be discussed.

Entrance allowance should be provided to UDEM authorized personel 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-



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- 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 exinting of application samples, the non-conformity will be classified as minor. Minor non-conformity does not need follow-up audit. It can be bssed on documents. The planning period of the corrective and prevetnive action is 15 days and closing period is approximately 3 months.
 3. **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.

Necessarry 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 personel 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 personel 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 personel and auditors.

Certificates: Confirmity certificates published by UDEM are controlled documents provided by is 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 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 the place of the owner of the organization, structure is changed. Demand should be in written for tranfers 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 accept 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.



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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 if 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.

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

You will be notified in writing if the certificate is withdrawn or suspended. When the situation that concerns the suspension or withdrawal of your certificate is resolved, you should inform us in writing that the nonconformity of the suspension has been removed. After this, an audit will be carried out to check that the nonconformity has been removed and the certificate will be renewed.

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.

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.

Withdrawal of Accreditation

Request for withdrawal of accreditation; The HAA may request written withdrawal of accreditation for its own reasons.

Withdrawal of Accreditation: A significant nonconformity during examination (full-time or writing-time) or during any other procedure may lead to withdrawal of accreditation.

The conformity assessment body reapplies to regain its status and implements a new accreditation procedure.

The accreditation application shall be made within 6 months of the date on which the accreditation is withdrawn.

If the accreditation of the conformity assessment body is withdrawn, the previously obtained certifications shall be submitted to the HAA.

In the event of loss of accreditation for suspension or withdrawal, we will notify our customers and prospective customers that suspension of accreditation and all accredited documents issued prior to withdrawal are suspended, all documents issued in suspension or withdrawal are non-accredited.



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Documents whose accreditation is suspended or withdrawn shall provide documents:

- a) Test reports, calibrations, inspection reports / certifications, certificates (no expiration date) are subject to change in the status of the accredited organization.
- b) Inspection reports / certifications and certifications with a certain validity period are valid until the end of the validity period, regardless of the change in the status of the accredited organization.
- c) Inspection certificates or certificates with a certain period of validity and periodic inspection are valid until the first inspection report to be issued by the acceding or withdrawing organization.
- d) The inspection reports / certifications received by an accredited inspection certification organization under the conditions of activity of the accredited organization.

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