

MANAGEMENT COMMITMENT



UDEM Adriatic d.o.o. facilitates management system certification and conformity assessment activities from October 05, 2015, by decision of the Commercial Court of the Republic of Croatia, and was registered in the court register under number MBS: 080992056, OIB: 50373079784.

This commitment is made by UDEM Adriatic d.o.o's top management. UDEM Adriatic d.o.o top management consists of UDEM Adriatic d.o.o owner and General Manager.

The top management of UDEM Adriatic d.o.o ensures that the quality management system is fully understood, implemented and maintained throughout the UDEM Adriatic d.o.o organization, including subsidiaries and subcontractors involved in conformity assessment activities according to 2017/745/EU MDR.

According to its policies, UDEM Adriatic d.o.o. is at the same distance towards all organizations. UDEM Adriatic d.o.o. established an impartial and independent structure in order to avoid all kinds of financial, administrative and other pressures that can affect activities and decisions about certification. During the certification activities carried out by UDEM Adriatic d.o.o. personnel, committees, auditors, product reviewers, clinical experts and technical experts must not be influenced by any person or organization.

UDEM Adriatic d.o.o. and its personnel are responsible for all aspects of document review and verification activities within the framework of the principle of confidentiality.

The personnel of the company UDEM Adriatic d.o.o. will maintain professional secrecy in the performance of their tasks in accordance with the Medical Devices Regulation 2017/745/EU or any provision of the national law that implements it, except in relation to the bodies responsible for notified bodies, the competent authorities for medical devices in the Member States or the Commission. Proprietary rights will be protected. The top management has the ultimate responsibility for the exchange of information with the competent authority and the accreditation body.

UDEM Adriatic d.o.o. operates in accordance with a set of consistent, fair and reasonable terms and conditions, taking into account the interests of small and medium-sized enterprises as defined in Recommendation 2003/361/EC in relation to remuneration.

UDEM Adriatic d.o.o. is capable of performing all tasks covered by 2017/745/EU Medical Devices Regulation with the highest degree of professional integrity and the necessary competence in the specific field.

UDEM Adriatic d.o.o. has the necessary personnel and owns and has access to all the equipment, facilities and competencies necessary for the proper performance of technical, scientific and administrative tasks involved in conformity assessment activities.

There is no relation between departments and functions of UDEM Adriatic d.o.o with any consultancy service, this kind of service is officially forbidden. Candidate clients shall declare the consultancy service which they received (if there is any) in writing and a conflict of interest analysis has been made.

Actions and services are carried out by competent personnel according to legal requirements, national and international rules and in parallel to expectations and needs of customers.

UDEM Adriatic d.o.o undertakes all kinds of authority and responsibility including certification, refusing, continuing of certification, renewals, extension, and reduction of scope, suspending or restoring following suspension and withdrawal of certifications, and these decisions shall not be subcontracted. Also, UDEM Adriatic d.o.o provides independence in the decisions of the certification committee.

UDEM Adriatic d.o.o top management will also be impartial in Product and System Certifications. UDEM Adriatic d.o.o top management, provides necessary trainings for all personnel to understand the importance of impartiality.

UDEM Adriatic d.o.o will regularly analyze any conflict of interest that threatens the impartiality of actions and provide understanding to all personnel. With this analysis, objectiveness will be provided in actions.

UDEM Adriatic d.o.o., by signing a contract with the personnel, ensures the loyalty of its personnel to perform certification activities according to the principles of confidentiality, openness, responsibility and authority.

UDEM Adriatic d.o.o, as a certification body, is not carrying out design, production, assembling, distribution, or maintenance services and is not part of a legal entity engaged in these processes and will not be. UDEM Adriatic d.o.o is a third-party body that is independent of the manufacturer of the device to which it performs conformity assessment activities. UDEM Adriatic d.o.o is independent of any other economic operator having an interest in the device as well as of any competitors of the manufacturer.

UDEM Adriatic d.o.o and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

All of the personnel in UDEM Adriatic d.o.o. have fixed monthly salaries. The level of the remuneration of the top-level management and assessment personnel of UDEM Adriatic d.o.o and subsidiaries and subcontractors, involved in assessment activities shall not depend on the results of the assessments.

UDEM Adriatic d.o.o, its top management and the personnel who carries out conformity assessment activities shall not:

- a) Be the designer, manufacturer, supplier, installer, purchaser, owner or maintainer of devices which they assess, nor the authorized representative of any of those parties. Such restriction shall not preclude the purchase and use of assessed devices that are necessary for the operations of UDEM Adriatic d.o.o and the conduct of the conformity assessment, or the use of such devices for personal purposes;
- b) Be involved in the design, manufacture or construction, marketing, installation and use, or maintenance of the devices for which they are designated, nor represent the parties engaged in those activities;
- c) Engage in any activity that may conflict with their independence of judgment or integrity in relation to conformity assessment activities for which they are designated;
- d) Offer or provide any service that may jeopardize the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacturer, its authorized representative, a supplier or a commercial competitor as regards the design, construction, marketing or maintenance of devices or processes under assessment, in the time they are designated or in the past 3 years (2 years for system certification), and
- e) Be linked to any organization which itself provides consultancy services as referred to in point (d). Such restriction does not preclude general training activities that are not client-specific and that relate to the regulation of devices or to related standards.

These rules are valid for system certification (ISO 9001 / ISO 13485) and MDR conformity assessment

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activities of UDEM Adriatic d.o.o.

Involvement in consultancy services in the field of devices prior to taking up employment with UDEM Adriatic d.o.o. shall be fully documented at the time of employment and potential conflicts of interest shall be monitored and resolved. Any involvement in processes (e.g. design, risk management, manufacturing processes) related to the devices and quality management systems for economic operators covered by the application/designation is seen as consultancy. Other activities not specifically linked with the product are also regarded as consultancy (e.g. internal audits to manufacturers or client-specific training).

Personnel who were formerly employed by a specific client, or provided consultancy services in the field of devices to that specific client before taking up employment with UDEM Adriatic d.o.o., shall not be assigned for conformity assessment activities for that specific client or companies belonging to the same group for 3 years. This period is applied as 2 years for UDEM Adriatic d.o.o.'s system certification activities.

UDEM Adriatic d.o.o. does not limit access based on the size of the client, membership in any groups, or the number of certifications already given.

To ensure customer satisfaction and respect for the organization, UDEM Adriatic d.o.o. will dedicate itself to the constant development and renewal of personnel.

Any planned action in the future related to UDEM Adriatic d.o.o.'s certification services will be completely independent of the influence of third parties.

During the provision of services, independence, impartiality and confidentiality principles will be based on meeting the necessities of standards and regulations to provide customer satisfaction at the highest level and to improve the respectiveness of UDEM Adriatic d.o.o in the national and international area.

With our systematic established based on national and international rules, analysis of independence, impartiality and confidentiality principles and situations that can cause conflict of interest and provision of resources are clearly defined and declared in our documents.

As UDEM Adriatic d.o.o, with our auditor pool within the scope of our system certification accreditation and Notified Body Designation under 2017/745/EU MDR, we carry out system certification and conformity assessment activities all over the whole world.

All personnel in UDEM Adriatic d.o.o (full-time or subcontracted auditors/technical experts/product reviewers/clinical experts and personnel of the subcontractors), and all committee members are independent, and they declare that they are away from any financial and other pressures. This situation is guaranteed with this commitment.

TOP MANAGEMENT

Company Owner

Ali Yücel KERİMOĞLU

General Manager

Zekeriya AYTAÇ