



MANAGEMENT COMMITMENT

UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi Sanayi ve Ticaret Anonim Şirketi operates as an accredited system certification body in the field of ISO 13485 management systems certification within the scope of TS EN ISO/IEC 17021-1 standard, accredited conformity assessment body in the within the scope of TS EN ISO/IEC 17065 standard, notified body authorized within the scope of 2014/33/EU Lifts Directive, 305/2011/EU Construction Products Regulation, 2006/42/EC Machinery Safety Directive, 93/42/EEC Medical Device Directive, (EU) 2017/745 Medical Device Regulation and accredited laboratory within the scope of TS EN ISO/IEC 17025 standard.

This commitment is given by UDEM A.Ş. senior management. Senior management at UDEM A.Ş. consists of General Manager Mustafa MEMİŞOĞLU, Coordinator Serian DOMA work directly under the General Manager and who can represent him.

The organizational structure of UDEM A.Ş., consisting of competent personnel in their field, is shown with the organizational chart. The duties, responsibilities and authorities of all personnel and committee members working within UDEM A.Ş. have been clearly determined with the job description documents defined in the quality management system and have been declared to the senior management, each personnel and committee member.

UDEM A.Ş. is not part of any other organization and/or larger organisation. It does not partially or wholly own legal entities residing abroad. UDEM A.Ş. does not have any representative body authorized to undertake a part of conformity assessment activities.

UDEM A.Ş. senior management ensures that the quality management system within the scope of conformity assessment activities in accordance with the (EU) 2017/745 Medical Device Regulation is fully understood, implemented and maintained throughout the organization, including affiliates and subcontractors involved in conformity assessment activities.

UDEM A.Ş. is able to fulfill all duties within the scope of the (EU) 2017/745 Medical Devices Regulation with the highest level of professional honesty and the necessary competence in a specific field.

It is declared with this commitment that if the customers of other companies owned by the company owner want to receive certification and test service from another company, the processes will not be affected by each other and will be carried out completely independently.

UDEM A.Ş. is at equal distance from all institutions in accordance with its policies. UDEM A.Ş. has established an impartial and independent structure that is free from any commercial, financial, administrative and other internal and external pressures that may affect the quality of the work for all certification and laboratory activities. No person or organization may affect the integrity of the personnel involved in the certification and testing activities carried out on behalf of UDEM A.Ş. regarding their decisions and works.



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UDEM A.Ş. and its personnel have adopted the principle of openness in all certification and test activities, and communication with the relevant enterprise and other parties within the framework of confidentiality principles. UDEM A.Ş. personnel must comply with professional confidentiality rules, with the exception of notified bodies, competent authorities for medical devices in member states or staff responsible for the commission. Property rights will be protected. The ultimate responsibility for the exchange of information with the competent authority and the accreditation body is under the senior management.

UDEM A.Ş. has all the personnel, equipment, facilities and competencies necessary to properly perform the technical, scientific and administrative tasks involved in the conformity assessment activities and has access to these resources.

UDEM A.Ş. has no relationship with consulting services in all its units and functions, and the provision of such services is officially prohibited. It is determined and analyzed in written from which institution the candidate customers receive consultancy services (if any).

Activities and services will be carried out by competent personnel in line with legal requirements, national and international rules and expectations and needs of customers.

UDEM A.Ş. undertakes all kinds of authority and responsibility including certification, refusing, continue of certification, renewals, extension and reduction of scope, suspending or restoring following suspension and withdrawal of certifications. These decisions can never be subcontracted. UDEM ensures that the Certification Committee takes its decisions on certification completely independently.

UDEM A.Ş. senior management will be impartial in certification and testing activities. UDEM A.Ş. senior management will provide the necessary training for each employee to understand the importance of impartiality.

UDEM A.Ş. will regularly analyze conflicts of interest that may threaten the impartiality of its activities and ensure that this analysis is understood by all its staff. Through this analysis, it will ensure objectivity in its activities.

UDEM A.Ş. will ensure that all of its personnel, who are responsible for carrying out certification/testing activities and taking decisions, will work in accordance with the principles of independence, confidentiality, openness, responsibility, sensitivity to complaints, competence and risk-based approach, especially impartiality, with contracts signed before starting work.



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As a conformity assessment body, UDEM A.Ş. is not and will not be part of any economic operator and legal entity performing the design, production, assembly, distribution or maintenance activities of the product whose conformity is assessed. UDEM is also a third-party organization structured independently of the manufacturer's competitors as well as other economic operators that have an interest in the product.

UDEM A.Ş. senior management and the personnel who carry out conformity assessment activities may not directly participate in the activities of the parties or their representatives involved in the design, manufacture or construction, marketing, assembly, use or maintenance of the lifts or lifts safety components evaluated. UDEM A.Ş. may not engage or participate in any activity that may adversely affect the independence of decision-making and fulfillment of professional requirements, in particular in relation to the activities for which notification is made, such as consultancy services.

UDEM A.Ş. senior management and the personnel who carry out the conformity assessment activities cannot be directly involved in the activities of the parties or their representatives who are involved in the design, manufacture, supply, installation, use or maintenance of the lifts or lifts safety components evaluated.

UDEM A.Ş. and its personnel carry out conformity assessment activities with a high level of technical competence and professional experience. It applies the decisions taken at the end of these activities independently of any kind of pressure, incentives and people that may be affected, especially financial issues.

The level of remuneration of UDEM A.Ş. senior management, the personnel carrying out the testing processes, the conformity assessment personnel and the subcontractors involved in the evaluation activities, does not depend on the results of the evaluations and the number of evaluations and the outputs of audits/assessments. While the wage amounts determined by UDEM A.Ş. are made with a fixed monthly payment for the internal personnel; payments are made for external personnel based on daily assessment/audit durations. UDEM A.Ş. senior management has a remuneration policy that will ensure the impartiality of itself and the evaluation personnel, periodically evaluates the potential risks that may arise from remuneration and takes the necessary measures.

UDEM A.Ş.'s personnel shall ensure professional confidentiality for all information obtained in conformity assessment activities defined in Annexes IV to Annex XII of 2014/33/EU, except in relation to the relevant ministry and the personnel protect the property rights of the information with respect to this information.

UDEM A.Ş. ensures the confidentiality, independence and impartiality of the conformity assessment activities carried out by the liaison offices and the subcontractors it has appointed to carry out some of the conformity assessment activities and ensures that these do not affect the independence, impartiality or objectivity of conformity assessment activities of UDEM A.Ş.



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UDEM A.Ş. senior management and personnel conducting system certification and conformity assessment tasks may not:

(a) Engage in any activity that is in conflict with the integrity of the conformity assessment activities or the independence of their decisions;

(b) Offer or provide services that could undermine confidence in independence, impartiality and objectivity. In particular, it has not offered consulting services to economic operators, commercial competitors, customers and companies belonging to the same group over the last 3 years on the legal requirements for the design, construction, marketing and maintenance of the product or processes under consideration. This does not preclude conformity assessment activities for economic operators and commercial competitors or general customer-specific training activities of medical device regulations or related standards. UDEM does not limit access based on size of the client, membership in any groups, or number of certifications already given. Financial conditions for certification shall not be undue to applicants.

(c) be the designer, manufacturer, supplier, installer, purchaser, owner or maintainer of devices which they assess, nor the authorised 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 A.Ş. and the conduct of the conformity assessment, or the use of such devices for personal purposes;

(d) be involved in the design, manufacture or construction, marketing, installation and use, or maintenance of the devices for which they are assigned or represent the parties engaged in those activities;

(e) engage in any activity that may conflict with their honesty and independence of decisions in relation to conformity assessment activities to which they have been assigned,

(f) offer or provide any services that could jeopardize the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacturer, the manufacturer's authorized representative, a supplier or a commercial competitor regarding the design, construction, marketing or maintenance of products or processes under assessment. (g) affiliated with any organization providing consultancy services as referred to in clause f. This restriction does not preclude general training activities that are not customer specific and related to the regulation of devices or related standards.

UDEM A.Ş. ensures that its services are accessible to all applicants whose activities fall within its operational scope.

Access to the certification process at UDEM A.Ş. does not depend on the scale of the client, membership of any association or group, or the number of certifications currently granted. UDEM A.Ş. works in accordance with a consistent, fair and reasonable set of terms and conditions, taking into account the interests of small and medium-sized enterprises, as defined in the regulation on the definition, qualifications and classification of small and medium-sized enterprises with respect to wages.

At UDEM A.Ş., no sacrifice will be spared for the continuous improvement and renewing of the personnel in terms of ensuring customer satisfaction and the prestige of UDEM A.Ş.

The processes to be carried out for complaints and appeals submitted to UDEM A.Ş. will be handled and examined within the scope of impartiality and independence.



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The services that UDEM A.Ş. plans to provide in the future will be realized completely independent of the certification services.

While providing services, the principles of impartiality, independence and confidentiality will be taken as a basis, and the requirements of the relevant standards, regulations and guides will be meticulously applied to meet the highest level of customer satisfaction and to increase the prestige of UDEM A.Ş. in the national and international arena.

Issues such as the principles of independence, impartiality and confidentiality, the analysis of situations that may cause conflicts of interest, the supply of resources, with the systematic that we have established in accordance with national and international rules are clearly stated and declared in our documents.

UDEM A.Ş. ensures the protection of customers' confidential information and registration rights, including the storage of electronic information and the transmission of test results.

As UDEM A.Ş., we have the auditors and technical personnel that can response to all applications from every province in Turkey. UDEM A.Ş. is responsible for meeting the requirements of the TS EN ISO/IEC 17025 standard and performing the test services in a way that meets the needs of the customer and legal authorities or organizations.

UDEM A.Ş.'s personnel, directors, owner, any organs of its subsidiaries or liaison offices do not provide consulting services in any way, including internal auditing and client-specific training.

UDEM A.Ş. undertakes not to engage in any commercial activity in the field of medical devices for which it provides certification services.

UDEM A.Ş. does not provide services to organizations that have kinship relations and jeopardize impartiality, so that kinship relations do not affect its activities.

UDEM General Manager and Related Unit Coordinators declare that they do not own a company in the field of medical devices and/or in a different field, do not engage in any commercial activity, do not have any family, personal and partnership ties that may lead to a conflict of interest with such companies and other companies belonging to the same group. They undertakes that they are not affiliated with an organization that provides consultancy services and that they will not provide consultancy services in any way.



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In addition, UDEM A.Ş. carries out conformity assessment activities all over the world within the scope of the medical device directive. Countries that are embargoed and not covered by our professional liability insurance are not included in our scope of activity (Russia, Belarus, North Korea, Syria, Sudan and Cuba).

UDEM A.Ş. personnel (certification/testing process employees, full-time or part-time auditors, technical experts and clinical experts) and all board & committee members are independent in all tasks they undertake. This declaration guarantees that they are free from commercial, financial and other pressures.

GENERAL MANAGER
MUSTAFA MEMİŐOĐLU
01.10.2024