



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 field of ready mixed concrete and~~ 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 made by the Senior Management of UDEM A.Ş. The Senior Management of UDEM A.Ş. consists of General Manager Mustafa MEMİŞOĞLU and Coordinator Serian DOMA, who reports directly to the General Manager and may act as his/her deputy **when necessary**.

UDEM A.Ş.'s organizational structure, comprised of competent personnel in their respective fields, is shown in the organizational chart. The duties, responsibilities, and authorities of all personnel and committee members working within UDEM A.Ş. are clearly defined in job description documents within the quality management system; these have been communicated to senior management, each employee, and each 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.



MANAGEMENT COMMITMENT

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. **Potential candidate** clients are **asked** in writing **during the application process** to provide information on which organization they received consulting services from (if any), and this information is analyzed.

All conformity assessment activities and services offered by UDEM A.Ş. ~~Activities and services~~ will be carried out by competent personnel **in accordance with** national and international **requirements rules**, and in line with the expectations and needs of the clients.

UDEM A.Ş. undertakes all kinds of authority and responsibility including certification, refusing, continue of certification, renewals, extention 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. assumes the authority and responsibility for decisions regarding certification activities, including granting, refusing, maintaining, expanding and narrowing the scope, renewing, suspending, restoring following suspension and withdrawing certification. These decisions can never be outsourced. UDEM A.Ş. ensures that its **personnel conducting final review and decision-making activities** ~~Certification Committee~~ make their certification decisions with complete independence.

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.



MANAGEMENT COMMITMENT

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.

~~As a conformity assessment body,~~ UDEM A.Ş. is not, and will not be, a part of any economic operator that designs, manufactures, assembles, distributes, markets, or maintains the products for which it conducts conformity assessment. Furthermore, **UDEM A.Ş.** is a third-party organization structured independently of the manufacturer and its competitors, **as well as other economic operators who may benefit from 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 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 examination/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 examination/assessment/audit durations. UDEM A.Ş. senior management has a remuneration policy that will ensure the impartiality of itself and the **conformity assessment 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



MANAGEMENT COMMITMENT

the relevant ministry (**competent authority**) 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 contact offices and the subcontractors assigned to carry out part of the conformity assessment activities. It also ensures that **the contact offices and subcontractors** do not affect the independence, impartiality, or objectivity of UDEM A.Ş.'s conformity assessment activities.

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. is not dependent on the applicant's size, membership in any association/society or group, or the number of certifications previously awarded. UDEM A.Ş. applies its fee policy in a consistent, fair, and reasonable manner, taking into account the definitions and classifications of small and medium-sized enterprises in the relevant legislation.



MANAGEMENT COMMITMENT

~~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. are ~~will be handled~~ **evaluated and concluded in accordance with the principles** and ~~and examined within the scope~~ of impartiality and independence.

All services that UDEM A.Ş. will provide **outside of its certification activities** will be **conducted** ~~realized~~ completely independently of 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 contact 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.



MANAGEMENT COMMITMENT

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~~ Coordinator 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 undertake that they are not affiliated with an organization that provides consultancy services and that they will not provide consultancy services in any way.

UDEM A.Ş. conducts **international** conformity assessment activities worldwide. However, UDEM A.Ş. does not operate in countries that are ~~embargoed~~ **outside the scope** of its professional liability insurance (Russia, Belarus, ~~Iran, North Korea, Syria, Sudan and Cuba~~) **and/or in countries that are not deemed safe and suitable as a result of risk assessments conducted by UDEM A.Ş.**

UDEM A.Ş. Senior Management is responsible for maintaining the necessary organizational structure, resources, and practices to protect impartiality and independence, and hereby undertakes that all UDEM A.Ş. personnel, board and committee members involved in certification/conformity assessment and testing activities will perform their duties in accordance with the principles of impartiality and independence, and will remain free from any commercial, financial, or other pressure and influence.

~~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.~~

REVISION TABLE:

Section No.	Revision Date	Rev. No.	Description of Revision
All document	22.08.2016	13	*Revision follow-up table has been added. **We have any activity within the scope of medical device conformity assessment in our offices in China, India, Korea (China Branch Office Suzhou Management Consulting Co. Ltd., India Branch Office for Product Certification RIR Certification Private Ltd., Korea Branch Office GRC (Global Registered Certification) We undertake that there are no subcontractors and that we do not use subcontracted services in this context' statement has been added. ***USA, Canada, Iran, Iraq, Sudan, Syria, North Korea, Democratic Republic of Congo, Somalia, Libya, Zimbabwe, Burma, Cuba, which are not geographically covered by UDEM Professional Liability Insurance, will not accept customers. Statement removed.
All document	22.11.2016	14	Arrangements have been made for greenhouse gas verification activities.
4. paragraph	17.01.2017	15	"UDEM has adopted the principle of openness in communication with the relevant business and other parties in all certification and verification activities, within the framework of confidentiality principles." Statement added.

4. paragraph 7.paragraph	01.12.2017	16	<p>UDEM follows the principle of openness in communication with the relevant business and other parties in all certification and verification activities; adopted within the framework of confidentiality principles. The ultimate responsibility for information exchange with the competent authority and accreditation body rests with top management.</p> <p>UDEM assumes the authority and responsibility for the decisions regarding certification and verification activities, including granting, rejecting, maintaining, renewing, expanding and reducing the scope, renewing, suspending and withdrawing the certification, the specified decisions can never be subcontracted.</p>
All document	20.02.2018	17	The Serbian Representation has been removed from the representations.
All document	04.10.2018	18	Definitions of inspection activities have been removed.
All document	05.02.2019	19	Yusuf Haldun Oğuz has been assigned instead of Zekeriya Aytaç
All document	26.06.2019	20	Corrections have been made regarding the activities of the South Korean and Chinese liaison offices.
All document	05.08.2019	21	All document gözden geçirilmiştir.
All document	02.01.2020	22	General Coordinator has been changed to Murat Can KERİMOĞLU.
All document	14.08.2020	23	The term "Notified Body" has been added by general review.
All document	10.11.2020	24	In the first paragraph of the commitment, the names of "2014/33/EU Elevator Regulation, 305/2011/EU Construction Materials Regulation, 93/42/EEC Medical Device Regulation and 2006/42/EC Machinery Safety Regulation" have been corrected.
All document	09.02.2021	25	The title of General Coordinator Murat Can Kerimoğlu has been revoked.
1. paragraph	01.03.2021	26	ISO 9001 has been removed.
All document	02.08.2021	27	It has been rearranged in accordance with the requirements of the 2017/745/EU Medical Device Regulation.
3.Paragraf	06.09.2021	28	The phrase "in the entire organization, including affiliates and subcontractors involved in conformity assessment activities" was added.
22.and 23.paragraph 28. paragraph	17.11.2021	29	<p>"UDEM ensures that its services are accessible to all applicants whose activities are within the scope of its operation." and "There can be no financial or other extreme circumstances." statements have been added.</p> <p>"Customers of other companies owned by the owner/shareholder of the company" was added.</p>
18.paragraph	01.12.2021	30	UDEM's remuneration policy and definitions regarding the impartiality of related activities have been updated.
2. paragraph	16.05.2022	31	It has been stated that the top management of UDEM consists of Mustafa MEMİŞOĞLU, the General Manager of UDEM.
Revision Table	12.09.2022	32	Information about the 26th revision has been added to the Revision Table.
All document	10.10.2022	33	The entire document has been reviewed, and a detailed description of the scope of activity, accreditation and authorization has been added. The commitment has been revised to comply with the 2017/745/EU Medical Device Regulation Annex VII requirements in general. In this context; Incorrect statements regarding liaison offices have been removed and it has been stated that they will not be used within the scope of MDR. Definitions in line with MDR requirements have been added to the issues related to personnel remuneration. The definition of top management has been updated according to the current structure. The phrase "belonging to the same group" for consultancy and other conflict of interest matters has been added to the appropriate sections. Instead of UDEM, UDEM A.Ş. has been named. A title has been added to the revision table.
Page 5	23.12.2022	34	Instead of the expression "management system consulting services", the expression "do not provide consulting services in any way" has been added.

Page 1 Page 5	09.05.2023	35	<p>In the first sentence of the document, “has been awarded with the Trade Registry Gazette dated 11.08.2017, numbered 9387 and with the registration number 182921” definition has been removed. The names of the Relevant Unit Coordinators (Serian DOMA, Duygu Meriç SATIR) that make up the senior management together with the General Manager have been added. Number and date of Trade Registry Gazette has been changed.</p> <p>The expression “<i>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.</i>” has been added.</p>
All Document	17.01.2024	36	Definitions regarding verification activities and the Coordinator role outside the Medical Device Unit have been removed from the document.
Whole document	22.02.2024	37	<p>Conformity assessment activities within the scope of (EU) 2017/745/Medical Device Regulation have been added to UDEM A.Ş.’s activities.</p> <p>The phrase "The activities of UDEM Pacific and UDEM China, which operate as UDEM's contact office, will not include product certification activities within the scope of the 2017/745/EU Medical Device Regulation." has been removed from the document as UDEM Pacific and UDEM China contact offices have started to operate within the scope of MDR.</p>
All document	01.10.2024	38	The definition of ready-mixed concrete activity in the document has been removed.
All document	25.03.2026	39	The document has been revised and clarified to reflect current practices and make it more understandable. Countries outside the scope of activity have been updated. The phrase "final reviewer and decision-maker involved in the certification decision-making process" has been added in place of "certification committee". The repetitive paragraph regarding elevator conformity assessment activities has been removed.