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1. PURPOSE

It is the definition of the pricing to be applied to the organizations that receive management system certification service from UDEM.

2. SCOPE

This instruction includes UDEM's fees as an indication that UDEM provides equal service to all its customers in accordance with the requirements of the TS EN ISO/IEC 17021 standard.

3. RESPONSIBLES

- General Manager
- Administrative and Financial Affairs Manager
- Certification Manager

4. DEFINITIONS

Man/day fee (Auditor/day fee): It is the fee of 1 auditor who will go to a 1 day audit.

5. APPLICATION

Customers/prospective customers must fill in the **FRM.81 Application Form for ISO 13485 Certification** in order to receive a price quote from UDEM.

5.1. Initial Certification Audit Fee: In order to determine the initial certification audit fee, the number of auditors/day must be determined according to the number of employees of the applicant organization in accordance with the relevant international accreditation rules. If changes in the client's qualifications are noticed as a result of the Stage 1 audit, the auditor time required for Stage 2 may change. In such a case, the customer may have to pay a different fee than the initial offer. In order not to leave the customer in a difficult situation and to prevent disputes, there is a clause expressing this situation in the **FRM.16.M ISO 13485 Certification Offer/Agreement Form**.

5.2. Surveillance Audit Fee: The fee for surveillance audits, which will be held at least once a year, is determined depending on the auditor's duration, just as it is for the first certification audits.

5.3. Re-assessment Audit Fee: The fee for recertification audits is also determined according to the auditor's duration, depending on the changes in the number of employees at the end of the customer's 3-year certification period.

5.4. Pre-audit Fee: If the company demands preaudit, fee needed to pay is **same as Stage 1 Audit**.

5.5. Follow-up Audit Fee: When required, follow-up audit fee is paid for nonconformities in audits. The follow-up audit fee is same as Stage 1 Audit fee.

5.6. Privacy Audits:

a) If an audit is required when the scope extension request is received, the fee of the audit is determined according to the auditor man/day fee determined for the surveillance audit. If the client agrees to combine the scope extension audit with the surveillance audit, the cost of the audit is determined depending on the client's conditions and qualifications at that time.



b) Man/day fee of short-term audits is same as Stage 1 Audit fees.

5.7. Integrated Audits: Man/ day numbers are calculated separately in integrated audits and UDEM has a right of additional discounting as % 30 according to the result.

5.8. Other situations: If UDEM deems it necessary to carry out an audit in cases such as suspension, withdrawal, or reduction of the certification of its customers, the auditor determines the man/day fee of these audits by taking the same as the surveillance audit.

Stage 1 audit period is calculated as a maximum of 30% of the certification audit period.

In the pricing applied by UDEM to its customers, first of all, the man/day duration of the audit is calculated with the help of the tables below.

5.9. According to the EA 2/17 document article 8.1.4; In case of demand of conformity assessment services to the manufacturer or his authorized representative, giving them general information in accordance with the regulations for the basis conformity and the costs as a result of this service; depending on the quality of given information and considering the time of the personnel that is authorized by UDEM during the information period, cost is calculated by UDEM Top Management and informed the customer.

The calculated man/day time is multiplied by the man/day fee. The number in Table 2, which is the annual document usage fee, is added to this fee. The number found is the initial certification fee.

If the audit type is surveillance audit, audit man/day time is calculated as 1/3 of the first certification fee.

If the audit type is recertification audit, audit man/day time is calculated as 2/3 of first certification fee.

KDV is not included in this fee. Travel and accommodation costs of the auditors and technical experts are the responsibility of the CUSTOMER. UDEM is entitled to 25% discount or addition due to certain reasons of VAT amount. Among these reasons; In case of agreement with the customer, the following may be included;

Table 1.1- Fee Table for companies residing in Turkey:

<u>NAME OF CERTIFICATE</u>	<u>MAN/DAY FEE</u>	<u>ANNUAL CERTIFICATE USAGE FEE</u>
ISO 13485	21.500 TL	21.500 TL

Table 1.2- Fee Table for companies not resident in Turkey:

<u>NAME OF CERTIFICATE</u>	<u>MAN/DAY FEE</u>	<u>ANNUAL CERTIFICATE USAGE FEE</u>
ISO 13485	3.000 Euro	3.000 Euro

Table 2- Auditor calculation table for ISO 13485 certification:

<u>Effective number of employees</u>	<u>Audit Duration Stage 1+ Stage 2</u>	<u>Effective number of employees</u>	<u>Audit Duration Stage 1+ Stage 2</u>
1-5	3	626-875	15
6-10	4	876-1175	16
11-15	4,5	1176-1550	17
16-25	5	1551-2025	18
26-45	6	2026-2675	19
46-65	7	2676-3450	20
66-85	8	3451-4350	21
86-125	10	4351-5450	22
126-175	11	5451-6800	23
176-275	12	6801-8500	24
276-425	13	8501-10700	25
426-625	14	> 10700	Follow progression above.

6. RELATED DOCUMENTS

1. FRM.81 ISO 13485 Application Form
2. FRM.16.M ISO 13485 Certification Offer/Agreement Form.

PREPARED BY	CONTROLLED BY	APPROVED BY
Medical Device Quality Management Responsible	Management Representative	General Manager

7. REVISION TABLE

Part No.	Revision Date	Rev. No.	Description of revision
All document	08.10.2018	12	Revision table has been added, fees are stated in TL.
Table 2-1 and Table 2-2	13.09.2019	13	ISO 13485 man/day fees have been revised.



CHARGING INSTRUCTION

All document	14.02.2022	14	References to ISO 9001 have been removed. ISO 13485 man/day fee and annual document usage fee have been revised.
All document	29.07.2022	15	Man/day fee and annual document usage fee have been revised.
All document	01.09.2022	16	All document has been reviewed and unused documents have been removed. References have been made to documents used in current practice.
Table 1.1 Table 1.2	06.01.2023	17	Man/day fee and annual document usage fee have been revised.
Whole document	10.07.2023	18	Fees have been revised. The method of payment clause has been added. Table of index, related documents and prepared by-controlled by-approved by table have been added.
Table 1.1 Table 1.2	10.01.2024	19	Man/day fee and annual document usage fee have been revised.
Table 1.1 Table 1.2	05.09.2024	20	Fees have been revised.