

## CHARGING INSTRUCTION



**1. OBJECTIVE:** The Objective is to define charging for companies that requested a management system certification service from UDEM Adriatic d.o.o.

**2. SCOPE:** This instruction includes the fees of UDEM Adriatic d.o.o. in accordance with requirements of EN/IEC 17021-1:2015 standard as an indication of the certification services of UDEM Adriatic d.o.o., which are the same for all clients.

**3. RESPONSIBLES:** General Manager, Administrative and Financial Affairs Manager, System Certification Manager.

#### **4. DEFINITIONS:**

**Man/day fee (Auditor/day fee):** 1 auditor performing an audit for one day is the basis for fee calculation. The man/day fee for UDEM Adriatic d.o.o. is **1.000 Euros for EN ISO 13485 and 300 Euros for EN ISO 9001.**

**5. APPLICATION:** Clients need to fill out an Application Form (**FRM.12, FRM.81**) in order to receive a price offer from UDEM Adriatic d.o.o.

**5.1- Initial Certification Audit Fee:** It is necessary to determine the man/day number according to a number of employees of the company in accordance with related international accreditation rules to determine the initial certification audit fee. If changes in client conditions were realized at the end of the Stage 1 Audit, the man/day can be changed for the Stage 2 Audit. When this is the case, the client needs to pay a fee for the difference between the submitted initial offer and the current offer. To avoid a situation where neither party would be put in an unfavorable situation, this procedure is explained in **FRM.16 Contract ISO 9001 and FRM.16 M QMS. Duration & Offer.**

**5.2- Surveillance Audit Fee:** The fee for surveillance audits, which will be carried out at least once a year, depends on the auditor's time and the amount for the initial certification audit.

**5.3.-Re-assessment Audit Fee:** The Fee for reassessment audits is determined according to audit time depending on changes in the number of employees at the end of the client's 3-year certification cycle.

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

**5.5-Follow-up Audit Fee:** When necessary, a follow-up audit fee is charged to follow up on non-conformities in audits. The fee for a follow-up audit is the same as for a Stage 1 audit.

#### **5.6- Extraordinary Audits:**

- a) If the audit is required upon demand for an extension of the scope, the audit fee is determined for surveillance audit according to the audit man/day fee. If the client

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approves a unified audit for scope extension and surveillance audit, the audit fee is determined depending on present-day conditions and client qualification.

b) The man/day fee for short-term audits is the same as Stage 1 Audit fees.

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

**5.8- Other situations:** If UDEM Adriatic d.o.o. regards the audit in some situations such as suspending, recalling, limiting the scope of client certifications, UDEM Adriatic d.o.o. is determined that man/day fee of the audits is same as the surveillance audit.

Stage 1 audit time is calculated as maximum 30 % of certification audit time.

Man/day time of the audit is calculated in UDEM Adriatic d.o.o. charging implemented to the clients thank to the tables below.

**5.9-** In accordance with Article 8.1.4 of document EA 2/17 M:2016; if the manufacturer or its authorized representative requires a conformity assessment service, UDEM Adriatic d.o.o. is obliged to provide general information related to the regulation on which the basis of the conformity assessment is based and the costs incurred within the scope of this service. The quality of the provided information and the time that the staff authorized by UDEM Adriatic d.o.o. will spend during the certification process are taken into account, and it is calculated by the top management of UDEM Adriatic d.o.o. and delivered to the organization requesting conformity assessment.

Calculated man/day time is multiplied with **1.000 Euros for EN ISO 13485 and 300 Euros for EN ISO 9001**. 100 € as application review and document examination charge and number for annual certificate usage fee in Table 3 are added. The calculated number is the initial certification fee.

If it is a surveillance audit, the number of man/days is calculated as 1/3 of the time of the initial certification audit.

If it is a re-certification audit, the number of man/days is calculated as 2/3 of the time of the initial certification audit.

VAT is not included in these charges. UDEM Adriatic d.o.o. has the right to make 25% discount or addition in the amount where there is no VAT due to certain reasons. The client pays charges for the transportation and accommodation of auditors and technical experts.

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**Table 1-Auditor Calculating Chart for EN ISO 9001:2015 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	1.5	626-875	12
6-10	2	876-1175	13
11-15	2.5	1176-1550	14
16-25	3	1551-2025	15
26-45	4	2026-2675	16
46-65	5	2676-3450	17
66-85	6	3451-4350	18
86-125	7	4351-5450	19
126-175	8	5451-6800	20
176-275	9	6801-8500	21
276-425	10	8501-10700	22
426-625	11	> 10700	Follow the progression above.

**Table 2 -Auditor Calculating Chart for EN ISO 13485:2016 Certification Auditors**

<u>Effective Number of Employees</u>	<u>Audit Duration Stage 1 + Stage 2 (days)</u>	<u>Effective Number of Employees</u>	<u>Audit Duration Stage 1 + Stage 2 (days)</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 the progression above.

**Table 3- Annual Certificate Usage Fee Table:**

<b>DOCUMENT NAME</b>	<b>ANNUAL CERTIFICATE OF USE FEE</b>
EN ISO 9001:2015	500 €
EN ISO 13485:2016	1.000 €