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1. PURPOSE

This instruction is intended to help the organizations that apply to the medical device product certification process, to prepare proposals for specific criteria for inspections and audits to be carried out.

2. RESPONSIBLE PERSONS

- General Manager
- Coordinator
- Medical Device Technical Regulatory Responsible
- Planning Responsible

3. IMPLEMENTATION

For customers within the scope of conformity assessment activities to be carried out on existing certificates as of the end of implementation date of 25 May 2021 Medical Device Directive, the relevant processes among the following are carried out depending on the nature of the product:

1- Quality Management System Site Audit
2- Technical File Evaluation
3- Clinical Data Evaluation
4- Evaluation of Products Containing Drugs
5- Software Evaluation
6- Machine Directive Evaluation

The fees for all evaluations are based on man/day fees. Observers, candidate auditors are not included in the man/day count. The calculation of the audit/evaluation duration is carried out according to the **UDTLM.35 MDD Audit Time Calculation Instruction**.

3.1. Surveillance Information Review Fee

Before the surveillance audits, the information about the customer organizations is evaluated on the Surveillance Information Forms and the audit period is determined according to the **UDTLM.35 MDD Audit Time Calculation Instruction**. In this context, customer organization's address information, supplier information, number of employees, product information, change notifications, etc. is reviewed. The review fee is 8.500 TL for domestic companies and 500 € for foreign companies.

3.2. QMS Audits

For all manufacturers whose conformity assessment process is carried out within the scope of the Medical Device Directive, a QMS audit should be carried out by the technical experts/auditors in order to verify the suitability of the production infrastructure and to verify the functioning of the quality management system. The duration of the QMS inspections vary depending on the number of employees, complexity of the production process, audit language, nonconformity profile of the customer, the existence of different sites and shifts.

Man/day fee for QMS Site Audit is 61.000 TL for domestic companies.

Man/day fee for QMS Site Audit is 3.500 € for overseas firms.

Note 1: The fees for the accommodation and transport of the auditors, and the test fees carried out by UDEM when necessary, are not included in the proposal, it is stated that under the contract signed with the manufacturer, and these fees will be demanded from the manufacturers as additional fees.

Note 2: If there is a combined audit (System Certification and Product Certification), a discount can be made. (This discount cannot exceed 20%)

3.3. Technical Documentation Evaluation

Technical Documentation Evaluation For all manufacturers whose conformity assessment process is under way within the scope of the Medical Device Regulation, a site audit should be carried out by technical experts/auditors, with the aim of the assessment of the technical documentation (clinical evaluation, compliance with the basic requirements, risk assessment etc.). The frequency and duration of these inspections vary depending on the risk class of the relevant group of medical devices.

The man/day fee for Technical Documentation is 61.000 TL for domestic companies.

The man/day fee for Technical Documentation is 5.000 € for overseas companies.

3.4. Clinical Data Evaluation

The time required for clinical data evaluation varies depending on the risk class of the device, having different components, the new technology inclusion status and the amount of clinical data. PSUR and PMCF processes are also evaluated within the scope of clinical evaluation.

Man/day fee for clinical evaluation is 89.000 TL for domestic companies.

Man/day fee for clinical evaluation is 7.000 € for overseas firms.

3.5. Evaluation of Products Containing Drugs

If the medical device whose conformity assessment process is under way includes a medical product, since no assessment is carried out within the scope of surveillance audits, no additional fee is determined for this process.

3.6. Evaluation of Products with Software

In case that the medical device on which the conformity assessment process is carried out contains software, the relevant technical expert / auditor in the MDS 7010 code can evaluate the technical file sections related to software validation in the office or in the site.

The man/day fee for software evaluation is 80.500 TL for domestic companies.

The man/day fee for software evaluation is 6.000 € for foreign companies

3.7. PSUR / PMCF Evaluations

Evaluations of PSUR, which are included in the PMS processes carried out within the scope of MDR Article 120 and whose reporting and update times vary according to the device risk class, are carried out by both the auditor and clinical experts. For PSUR assessments, a technical file review fee is applied for auditors, and a clinical assessment fee is applied for assessment conducted by clinical experts. PMCF report evaluations

are carried out by clinical experts. For the evaluation carried out by clinical experts, clinical evaluation fee is applied.

The man/day fee for PSUR/PMCF evaluation is 71.000 TL for domestic companies.

The man/day fee for PSUR/PMCF evaluation is 6.000 € for foreign companies.

3.8. Surveillance Audits

Supervision audits include QMS site management, evaluation of technical documentation, evaluation of clinical data and any related additional audits. Pricing for supervision audits is calculated according to the man/day prices of the relevant assessments mentioned above. Reporting, certification and annual usage fees for survaillance audits are listed in the table below.

TABLE 1. Certification Annual Usage Fees

Device Class	Class I	Class IIa	Class IIb	Class III *	Class III * (Devices within the scope of MDS 7001 code)
Domestic Companies Price	31.000 TL	47.000 TL	62.500 TL	78.000 TL	156.000 TL
Overseas companies Fee	2.500 Euro	3.500 Euro	5.000 Euro	6.000 Euro	8.500 Euro

Notes:

According to the product risk class within the scope of the certificate, the above-mentioned fees are increased at the following rates according to the number of products.

a. If 3-5 products; 20%

b. If 5-10 products; 30%

c. If >10 products; 50%

2. If a different location check will be made abroad; annual document usage fee is increased by 20%.

3. If there are devices in more than one class within the scope of sampling, the annual document usage fee is calculated for highest class devices.

3.9. MDD-MDR Integrated Audits

In the case that MDD surveillance audits can be carried out in integration with MDR initial certification audits, in addition to the assessments carried out within the scope of MDR, at least 1 man/day if the products are the same, and at least 1.5 man/day if the products are substitutes, in addition to the MDR audit period, in order to examine the changes to the relevant products and processes within the scope of MDD surveillance and/or to examine the effectiveness of the activities related to previous audit nonconformities, if any. In this context, the fees for integrated audits are generally calculated according to site audit and annual certificate usage fees.

3.10. Customer Support

Pursuant to Article 8.1.4 of EA 2/17; the expenses to be incurred due to the general briefing of the manufacturer or its authorized representative about regulation on which the evaluation is based, and additional expenses to arise due to this service; shall be calculated by the top management of UDEM and shall be submitted to the requesting institution by taking into consideration the nature of the information provided and the time spent by the personnel to be authorized by UDEM during the information process.

3.11. Unannounced Audit Fees

The unannounced inspections are carried out with at least two auditors, one day at least every 3 years in accordance with the relevant legislation. The frequency of unannounced inspection may be increased in certain situations as defined in the relevant instruction / procedure. Unannounced inspection fee;

- For domestic companies; *141.500* TL (per audit)
- For foreign companies; *8.500* Euro (per audit)

3.12. Short-term Audits

After the complaint received by us, the Ministry's notification etc., short-term audits may be required in the company for the purpose of researching and examining the relevant issue. Pricing for short-term audits is carried out as in Section 3.9.

3.13. Additional Supplier Audit Fees

In cases where the customer wants to add or change a new supplier; in addition to the man/day fee for the audits carried out at the supplier, if the audit will be carried out on the basis of documents, half of the annual fee for the additional surveillance audit will be taken for the reporting made within the scope of the audit carried out and the total assessment fee will be reflected to the customer organization. However, if on-site or remote site audit is required, an audit planning and reporting fee of 62.500 TL will be applied for domestic companies and 2.000 Euro for foreign companies. (All conformity assessment activities of manufacturing companies with suppliers abroad are carried out in Euro currency.)

3.14. Change Notification Review Fees

After the notification of the changes that the customer plans to make in the quality management system or technical file, the site audit or office inspection period to be performed is determined and the examination fee is calculated over the man-day fees specified above for the relevant processes. For the reporting made within the scope of the conducted examination, the total evaluation fee is reflected to the customer organization by taking half of the annual surveillance audit cost.

3.15. Administrative Fees

In addition to the above-mentioned charges, UDEM will also charge for the following administrative services:

Price Type:	**Domestic**	**Overseas**
Change Confirmation Forms	36.000 TL	2.500 €
Certificate copies	8.500 TL	250 €

Additional certificate copies (for each of the requests above 10 copies)	1.500 TL	40 €

3.16. Exceptions

UDEM is entitled to make maximum 10 % (for domestic clients and for cash payments) and 20% (for overseas clients) discount or addition on the amount before VAT due to certain reasons. Among these reasons; the points below may be included if agreed with the customer;

- Multi-site controls for the Customer (increased time spent on the road)
- Ease or difficulty of access to customer location (increase/decrease of time spent on the road)
- May be increased if accommodation/transportation is covered by UDEM, and similar instances apply.
- In case of small and medium-sized companies.

3.17. Payment Method

For the conformity assessment activities carried out within the scope of appropriate surveillance audit, the entire service fee specified in the **UDFRM.179-1 MDD Surveillance Audit Offer Form** is paid by the customer at least 15 days before the audit/evaluation.

4. RELATED DOCUMENTATION

- UDTLM.35 MDD Audit Time Calculation Instruction
- UDFRM.179-1 MDD Surveillance Audit Offer Form

PREPARED BY	CONTROLLED BY	APPROVED BY
Technical Regulation Responsible	Management Representative	General Manager