MEDICAL DEVICES REGULATION CONFORMITY ASSESSMENT CHARGING INSTRUCTION

1. PURPOSE

This instruction has been prepared to create offer according to certain criteria for examination and audits to be performed on applicants for the medical device product certification process.

2. REFERENCE

2017/745 Medical Devices Regulation Article 50, Annex 7 Cl.1.2.8, 2003/361/EC Commission Recommendation

3. RESPONSIBLES

- General Manager
- Medical Devices Technical Regulation Responsible
- Planning Responsible

4. IMPLEMENTATION

For customers who apply for CE product certification, the following processes are carried out according to the qualification of the product:

1- Quality Management On-Site Audit
2- Technical Documentation Review
3- Clinical Evaluation Assessment
4- Microbiological Evaluation
5- Software Validation Evaluation
6- Evaluation of product incorporating medicinal substance and/or absorbable substances

Fees of all assessments are based on man / day fee. Observers, candidate auditors are not included to man / day number.

3.1. QMS Assessments / Audits (MDR Annex IX Chapter 1 and PART A OF ANNEX XI OF MDR)

Every EU Quality Management System Certificate/EU Quality Assurance Certificate must be maintained by a minimum required number of annual audit days. Audit fees are calculated by multiplying the number of audit days required, taking account of the recommendations in

ISO 17021 and IAF MD 5 - 9, by the UDEM Adriatic d.o.o day rate. At the selection of the manufacturer, visits may be at 6- or 12-month intervals and will normally accumulate to approximately 30% (at a minimum) of the days required for a full initial assessment each year. However, on re-certification a reassessment of approximately 60-70% of the full initial assessment is required.

For QMS On-Site Audits man/day fee 2.000 €

Note 1: The auditor's travel, accommodation fees, when necessary test fees carried out by UDEM Adriatic d.o.o are not included in the offer and fee. It is defined in the contract signed with the manufacturer **(UDFRM.07.M Product Certification Offer Contract**) that these fees will be met by the customer as an additional fee.

Note 2: If it is integrated audit (System Certification and Product Certification), discount can be realized. (This discount can not exceed 20%).

3.2. **Technical Documentation Assessment / On-Site Audit**

The review of the technical documentation requires the highest levels of technical expertise. Product reviewers shall evaluate technical documentation, where applicable sampling of the technical documentation will be applied (including detailed assessment of ~~clinical~~ design and production data, essential requirements compliance, risk assessments etc.). The frequency and duration of this activity will depend on the range of risk classification of medical devices.

For technical documentation evaluation on- site audit man/day fee 3.200 €.

3.3. **Clinical Data Review**

The review of clinical data requires specific clinical expertise and the amount of time involved for these reviews depends on the novelty of device and the amount of clinical data required.

For clinical evaluation man/day fee 5.000 €

3.4. **Microbiological Evaluation**

Where a manufacturer is involved in the production of sterile devices a Site auditor under MDT 2008 is required to visit the relevant facilities. The expert will review sterilization data

and assess the appropriateness of manufacturing / environmental conditions for the production of devices that are intended to be sterilized.

For microbiological evaluation man/day fee 2.000 €

3.5. Evaluation of product incorporating medicinal substance and/or absorbable substances

Where the device incorporates a medicinal substance and/or devices that are composed of substances or combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body a product reviewer for MDS1001 and/or MDS 1008 is required to assess the related part of the technical documentation on-site or off-site.

For evaluation of product incorporating medicinal substance and/or absorbable substances man / day fee 10.000 €

3.6. Software Validation Evaluation

Where the medical device is a stand-alone software or an active device works by software product reviewer for MDS1009 is required to assess the related part of the technical documentation on-site or off-site.

For Software Validation Evaluation man/day fee 3.200 €

3.7. Annual Certification Fee

Annually each CE Marking certificate holder is charged a CE Marking Annual Management Fee. This is calculated by taking account of client complexity, number of sites, approved subcontractors and the specific range of products. As a medical device Notified Body, we are required to maintain and expand our core device expertise to cover all devices for which we are designated. This core competence is required to maintain the confidence of the regulatory authorities in UDEM Adriatic d.o.o's ability to make safe and sound judgments regarding devices and their compliance with the General Safety and Performance Requirements of the Regulation. The CE Marking Annual Management Fee provides the resources to support this activity by allowing UDEM Adriatic d.o.o staff to attend relevant professional meetings, briefings and standards / regulatory meetings and training and re-qualification of personnel. The Annual Management Fee also covers the management and review of every client file / client history / certificate to confirm the integrity of UDEM Adriatic d.o.o's CE Marking decisions and conformity assessments on an ongoing basis and

several witnessed audits. Included in the Annual Management Fee are a number of hours of free support to the manufacturer, which includes time for correspondence (email, written, telephone etc), telephone conference meetings and investigating of vigilance / regulatory and other related issues. The approximate certification fees are as below:

Class	Class I	Class IIa	Class IIb	Implantable IIb /Active (Rule 12) IIb Devices	Class III /
Fee	1000 €	1500 €	2000 €	2500 €	3000 €

* According to the MDR Annex 7 – Cl.1.2.8 and 2003/361/EC Commission Recommendation in additional to the table above for the SMEs (Small Medium Enterprises) follow discount will be applied:

- %30 discount for Micro Enterprises
- %20 discount for Small Enterprises
- %10 discount for Medium-Sized Enterprises

*Note: In accordance with Recommendation 2003/361/EC;

-The category of micro, small and medium-sized enterprises (SMEs) is made up of enterprises which employ fewer than 250 persons.

-Within the SME category, a medium sized enterprise is defined as an enterprise which employs fewer than 250 persons. (50-250 personel)

-Within the SME category, a small enterprise is defined as an enterprise which employs fewer than 50 persons. (10-49 personel)

-Within the SME category, a microenterprise is defined as an enterprise which employs fewer than 10 persons. (1-9 personel)

Enterprises which emploies more than 250 persons are considered “big enterprises” and the discount applied for SMEs is not applied to these companies.

3.8. **Surveillance Audits**

Surveillance audits involve QMS on-site audits, technical documentation assessment and relevant additional assessments such as microbiology assessment etc.

3.9. **Unannounced Audits**

UDEM ADRIATIC randomly performs unannounced audits on the site of the manufacturer and, where appropriate, of the manufacturer's suppliers and/or subcontractors, to verify the continuity of compliance with legal requirements. These audits are carried out MINIMUM once every five years or once in the certification period, at least one day and with at least two auditors.

3.10. **Renewal of Certificates**

Certificates for CE Marking (quality Management system / quality assurance / technical documentation assessment) are normally issued for at most 5 years, after the certificates expire and to renew there is a renewal process that must be completed. Manufacturers are responsible for requesting renewal and will be required to provide supporting documentation.

5 year Renewal Fee EU Quality Management System Certificate	3000 €
4 year Renewal Fee EU Quality Management System Certificate	2500 €
3 year Renewal Fee EU Quality Management System Certificate	2000 €
5 year Renewal Fee EC Quality Assurance Certificate	4000 €
4 year Renewal Fee EC Quality Assurance Certificate	3500 €
3 year Renewal Fee EC Quality Assurance Certificate	3000 €
5 year Renewal Fee EU Technical Documentation Assessment Certificate	6000 €
4 year Renewal Fee EU Technical Documentation Assessment Certificate	5000 €
3 year Renewal Fee EU Technical Documentation Assessment Certificate	4000 €

3.11. **Customer Support:**

In accordance with Article 8.1.4 of the EA 2/17 guide document and section 1.2.9 of Annex VII of MDR; if the manufacturer or its authorized representative requests the conformity assessment service, general information related to regulation which is the basis of assessment and the costs incurred within the scope of this service; taking into account the qualification of the information provided and the time that personnel will be authorized by the UDEM Adriatic d.o.o during the informing process, shall be calculated by the UDEM Adriatic d.o.o general manager and submitted to the requesting organization.

3.12. **Administration Fees:**

In addition to the fees detailed above there are a number of administration fees charged by UDEM details below:

Certificate re-issue (minor changes)	300 €
Copies of certificates	100 €
Additional copies above 10 (each)	10 €

3.13. **Travel Cost**

Travel Time	100 € / hour
Accommodation	Arranged by UDEM Adriatic according to the contract or provided by Client (min. ****Class accommodation)
Daily Allowance	100 €

3.14. **Other Costs**

1. Test and all related costs about the testing of the product are paid by the CUSTOMER.

2. Medical devices which need the consultation process of the competent authority and/or EMEA and/or EXPERT PANEL (according to the Article 54 of MDR) fees belong to CUSTOMER.

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Part No.	Rev. Date	Rev. No.	Description of Revision
All document	25.02.2019	01	Red marks are added.
3.4.	11.04.2019.	02	Change to 0,5 man/day.
The whole document	26.08.2019	03	The inconsistence has been eliminated in whole document "UDEM" is changed as "UDEM Adriatic d.o.o" and red parts are added into the document and wrong definitions and unnecessary parts are deleted. Regulatory Officer has been changed as "Regulation Responsible", UDEM has been changed " UDEM Adriatic d.o.o." Technical expert has been changed as "Product Reviewer" and auditors as "site auditors". The document has been updated to remove the term "design dossier". And UDTLM.17-1 MDR-Conformity Assessment Charging Instruction has been reviewed and updated to have a fee structure incompliance with MDR Annex VII section 4.2. The revision is made the regarding the NCR detected during Ministry Health and EU Commission Joint Assessment
All Fees	18.12.2020	04	All audit man/days arranged according to the current position in the Conformity Assessment Market.
2.Referance	20.09.2021	05	Annex 7 Cl.1.2.8, 2003/361/EC Commission Recommendation added

3.7. Annual Certification Fee	20.09.2021	05	According to the Annex 7 Cl.1.2.8, 2003/361/EC Commission Recommendation some discount applied to the Certification Fees. - Active (Rule 12) IIb Devices Defination was Corrected at the Table
3.9. Unannounced Audits	20.09.2021	05	Clause 3.9 added for Unannounced Audits and following clauses numbers changed.
3.15. Other Costs	20.09.2021	05	Test and Article 54 - Consultation Procedure Fees added.
3.1.	20.09.2021	05	IAF MD Defination added.