Fees Ordinance
Relating to the Medical Devices Act (MDA) and the statutory instruments for its implementation
(MDA Fees Ordinance)

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"Medizinprodukte-Gebührenverordnung vom 27. März 2002 (BGBl. I p. 1228), die zuletzt durch Artikel 4 der Verordnung vom 10. Mai 2010 (BGBl.I p. 542) geändert worden ist" / "Medical Devices Fees Ordinance of 27 March 2002 (Federal Gazette I p. 1228) last amended by Article 4 of the Ordinance of 10 May 2010 (Federal Gazette I p. 542)".

Introductory formula

On the basis of Section 37 sub-sections 9 and 11 sentence 1 and sub-section 12 sentence 3 Medical Devices Act of 2 August 1994 (Federal Gazette I p. 1963), revised by Article 1 no. 32 of the Act of 13 December 2001 (Federal Gazette I p. 3586), in connection with the second part of the Administrative Cost Act (*Verwaltungskostengesetz*) of 23 June 1970 (Federal Gazette I p. 821), the Federal Ministry of Health, in agreement with the Federal Ministry of Economy and Technology, orders the following:

Section 1 Scope

The competent federal higher authority charges fees and expenses for official acts under the Medical Devices Act and the statutory instruments issued for the implementation of the Act, in accordance with the following provisions.

Section 2 Authorisation, renewal and variation of authorisation

(1) The following fees are charged for decisions on:

1. authorisation of a medical device pursuant to Section 11 sub-section 1 sentence 1 MDA: 2 500 to 10 300 €
2. variation of authorisation of a medical device pursuant to Section 11 sub-section 1 sentence 1 MDA: 100 to 1 100 €
3. renewal of authorisation of a medical device authorised for a limited period pursuant to Section 11 sub-section 1 sentence 2 MDA: 100 to 1 100 €

(2) If authorisation is applied for simultaneously for a number of similar medical devices pursuant to Section 11 sub-section 1 sentence 1 MDA, the decision on the authorisation of the first assessed medical device is charged in accordance with sub-section 1 no. 1. The fees for any further authorisation may be reduced provided the similarity of the medical devices has diminished the time and effort taken for assessment so that the reduction is justified. However, the minimum fee to be charged for each further decision on the authorisation amounts to 1 100 €.

Section 3 Classification and differentiation of products

Fees for decisions on the classification of medical devices and their differentiation from other products, pursuant to Section 13 sub-sections 2 and 3 MDA, range from 200 to 1 000 €.

Section 4 Consultation procedures

(1) Decisions as a result of consultations, pursuant to Annex II sub-paragraph 4.3 or Annex III sub-paragraph 5, both in connection with Annex I sub-paragraph 7.4 of Council Directive 93/42/EEC of 14 June 1993 relating to Medical Devices (Official Journal EC no. L 169 p. 1), last amended by Directive 2000/70/EC of the European Parliament and the Council of 16 November 2000 (Official Journal EC no. L 313 p. 22), in connection with Section 4 or Section 6 of the Ordinance relating to Medical Devices, are charged as follows:

1. in the case of a new substance or a known substance with a new purpose	5 000 to 50 000 €
2. in the case of a known substance used in the traditional way	5 000 to 20 000 €

(2) In the case of several consultation procedures taking place within one certification procedure the fees for the follow-up consultations may be reduced to 25 per cent of the scheduled fee. If several consultation procedures concerning similar medical devices are requested at the same time, the fee for the decision on the first medical device is fixed in accordance with sub-section 1. The fees for the follow-up consultations may be reduced provided the similarity of the medical devices has diminished the time and effort taken for assessment so that the reduction is justified. However, the minimum fee to be charged for each further consultation amounts to 1 250 €.

Section 5 Official acts in connection with clinical investigations

(1) Fees for the authorisation of a clinical investigation, pursuant to Section 20 sub-section 1 in connection with Section 22a sub-section 1 MDA, range from 3 000 to 6 130 €.

(2) Fees for a requested assessment of an essential variation in the investigational protocol, pursuant to Section 22c sub-section 2 MDA, range from 600 to 1 630 €.

(3) Fees for the review of a request for exemption from the authorisation requirement in the case of medical devices with a negligible safety risk, pursuant to Section 20 sub-section 1 sentence 2 MDA in connection with Section 7 sub-sections 1 and 2 of the Ordinance relating to clinical investigations of medical devices of 10 May 2010 (Federal Gazette I p. 555), range from 400 to 700 €.

Section 6 Counselling

Fees for counselling of the responsible person, pursuant to Section 5 MDA, of notified bodies and sponsors, pursuant to Section 32 MDA, range from 500 to 2 800 €.

Section 7 Fees for special cases

(1) If

1. an application for an official act subject to a fee is withdrawn after its material processing has been started and before its completion, or
2. an application is rejected for other reasons than for incompetence, or
3. an official act is withdrawn or revoked,

fees are charged in accordance with Section 15 sub-section 2 of the Administrative Cost Act (*Verwaltungskostengesetz*).

(2) If the applicant has given cause for it, fees for revocation or withdrawal of an official act, notwithstanding sub-section 1 no. 3, range from a minimum of 50 € to a maximum equalling the fee fixed for the official act revoked or withdrawn.

(3) Fees for the partial or complete rejection of an objection to a material decision range from a minimum of 100 € to a maximum equalling the fee fixed for the official act objected to. This does not apply if the objection is only without success because the infringement of

an administrative or formal rule is irrelevant pursuant to Section 45 of the Administrative Procedures Act (*Verwaltungsverfahrensgesetz*).

(4) If an objection is withdrawn after its material processing has been started but before its completion, fees range from a minimum of 50 € to a maximum of 75 per cent of the fee fixed in accordance with sub-section 3.

(5) Fees for the partial or complete rejection and for withdrawal of an objection raised exclusively to the decision on the fees and expenses, range from a minimum of 50 € to a maximum of 10 per cent of the contested sum of money.

(6) If an objection is completely rejected as inadmissible, fees range from a minimum of 50 € to a maximum of 100 € in accordance with sub-sections 3 and 5.

(7) If an objection is partly rejected, fees payable in accordance with sub-sections 3 and 5 are reduced in proportion to the part that has been accepted; the fee may not fall below the minimum fee determined in sub-sections 3 and 5.

Section 8 Other fees

The below-listed official acts performed on application are charged as follows:

1.	scientific commentary and expertise	200 to 1 000 €
2.	advice that is not of a simple nature in written form	100 to 500 €
3.	certifications	25 €
4.	copies and duplicates	
	a) a basic fee, unless settled in connection with the official acts in accordance with numbers 1 and 2, of	20 €
	b) each copy	0.5 €
5.	inspection of files, except in the case of a pending objection procedure	25 to 250 €

Applicants should be informed that an official act pursuant to sentence 1 is subject to a fee.

Section 9 Determination of fees

Where this Fees Ordinance provides for skeleton rates, the individual fee is determined in accordance with Section 9 sub-section 1 of the Administrative Cost Act.

Section 10 Reduction and waiving of fees on application

The fees charged in accordance with Section 2 can be reduced on application by the debtor of the fee up to one quarter of the scheduled fee if the applicant cannot expect an economic benefit adequate to the scheduled fees, or if the cases are rare or the target group is small for which the medical device is intended to be used. Charging of fees can be waived entirely if the expected economic benefit is very low in proportion to the fees.

Section 11 Increase and reduction

In the case that a fee-involving official act pursuant to Sections 2 to 6 and 8 numbers 1 and 2 requires an exceptionally great deal of time and effort, the scheduled fee can be increased up to the double, and where skeleton rates exist up to the double of the relevant maximum rate. If such an increase in the payable fee is to be expected the debtor of the fee shall be heard. In the case that a fee-involving official act according to sentence 1 requires exceptionally little time and effort the fee may be reduced to 50 €.

Section 12 Expenses

Expenses are to be reimbursed in accordance with the provisions of the Administrative Cost Act.

Section 13 Transitional provisions

For official acts performed prior to the entry into force of this Ordinance, fees can be charged in accordance with the present provisions in so far as a decision on the costs has been explicitly reserved during the official act with reference to the impending issuance of this Ordinance.

Section 14 Entry into force

This Ordinance shall enter into force on the day after its announcement.