MDCG 2023-2

List of standard fees

January 2023

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

Introduction

Article 50 of Regulation (EU) 2017/745 on Medical Devices (MDR) and Article 46 of Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR) establish the requirement for notified bodies to make their standard fees publicly available: "Notified bodies shall establish lists of **their** standard fees for the conformity assessment activities that they carry out and shall make those lists publicly available". Neither the MDR nor the IVDR do provide any definition of "standard fees" itself.

When setting their fees, Notified Bodies also need to consider Annex VII 1.2.8 of the MDR and IVDR about their terms and conditions being fair and reasonable and taking into account the interest of small and medium-sized enterprises as defined in Recommendation 2003/361/EC.

Publication of "Lists of Standard Fees"

MDCG clarified the meaning of "publicly available", which "implies that a member of the public can access this information at any point in time, without the need for additional steps." (MDCG guidance 2019-6 section V.2.). This implies the list of fees of each notified body should be directly and easily accessible on the website of the notified body without any additional steps, e.g. without the need to register as a user of the website or provide contact data. This website should be the website registered for the notified body on NANDO and not a different website of another organization. The format of the standard fee table could be any that is accessible on a common website browser.

The currency shown should be relevant to the country where the notified body has its registered place of business (in line with the information provided in NANDO). If there are regional differences in fees charged depending on the location of manufacturer, this should also be indicated.

Language

The list of standard fees should be written in the same language as the website of the notified body. In case of multiple language formats, the list should be also available in the same languages[1].

[1] See also MDR / IVDR Annex VII section 2.2 "Where documents are used in various languages, the notified body shall ensure and control that they have the same content."

Scope and explanation for "List of Standard Fee" items

The templates for "List of Standard Fees" provided in this guidance document are intended to assist notified bodies defining their list of fees for publication in accordance with MDR Article 50 and IVDR Article 46. Notified bodies can decide the way how they charge for their services and should have documented procedures relating to fees charged for conformity assessment activities. The fee setting should be transparent, items should be clearly indicated in the published list of standard fees. The list of fees may include but is not limited to the items listed below. The published list needs to cover all activities corresponding to the scope of the notified body's designation and the conformity assessment activities which are regularly offered.

Fees can be charged as

- "**flat fees**", i.e. fixed fees that do not depend on the time and resources needed but which should adequately be based on actually incurred costs
- "**time-based fees**", i.e. fee items based on the time allocated for the activity.

Notified bodies should indicate the type of fee for each fee item, i.e. if it is fixed or time based. In addition to such fees, duly justified external costs should be claimed as expenditure (e.g. travel expenses, costs for external testing).

In case fees depend on factors other than time, those should be clearly stated. It is possible to express the expected fees as a range (minimum to maximum value for each fee item), indicating the factors that influence the fee to be paid. Overall, for each item shown, these factors should allow for a rough estimation of the overall cost for the respective conformity assessment activity.

Notified bodies should also indicate how the interests of small and medium-sized enterprises as defined in Recommendation 2003/361/EC are taken into account.

The quotation and fees actually charged, including individual items for an individual project, can be different for individual devices due to factors not considered in a list of standard fees. In case of substantial difference between the quotation and the final fee charged, notified bodies should notify manufacturers about the discrepancy and duly justify this adjustment.

Medical Devices

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List of Standard Fees for Conformity Assessment Activities under the MDR (2017/745), Notified body XXXX (NB No)

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	Type of Fee[1]	Fee in local currency	Factors influencing the calculation of fee charged[2]	Fee range(min-max)[3]
Administrative charges				
• Application fee	Flat Hourly Daily			
• Administrative fee related to changes	Flat Hourly Daily			
• Annual certificate maintenance fee (provide details which activities covered)	Flat Hourly Daily			
• Other (specify)	Flat Hourly Daily			
Travel timecosts (excluding expenses such as hotel costs)	Flat Hourly Daily			
Administrative costs related to handling of external services (laboratories, consultation or travel expenses)	Flat Hourly Daily			
Auditing				
• Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier)	Flat Hourly Daily			
• Unannounced Audit	Flat Hourly Daily			
Product testing				
• Laboratory testing (including preparation and reporting but excluding expenditures incurred for external tests)	Flat Hourly Daily			
Documentation Review				
• Technical documentation assessment[4]	Flat Hourly Daily			
• Clinical evaluation report assessment (CEAR)	Flat Hourly Daily			
• Expert panel consultation[5]	Flat Hourly Daily			
• Validation of the Summary of Safety and Clinical Performance (SSCP)	Flat Hourly Daily			

	Type of Fee[1]	Fee in local currency	Factors influencing the calculation of fee charged[2]	Fee range(min-max)[3]
• Consultation with medicinal product authorities[5]	Flat Hourly Daily			
• Consultation with human tissue and cells competent authority[5]	Flat Hourly Daily			
• Consultation with the coordinating competent authority for devices utilizing animal tissues[5]	Flat Hourly Daily			
• Evaluation/review of the Periodic Safety Update Report (PSUR)	Flat Hourly Daily			
• Assessment of changes	Flat Hourly Daily			
Reporting (if not covered above)	Flat Hourly Daily			
Special conditions for manufacturers belonging to SME as defined in Recommendation 2003/361/EC [6]				

[1] Please delete parts not applicable

[2] Based on the notified body's methodology for issuing quotations the relevant factors influencing the calculation should be indicate, for example the complexity of the device and the technical documentation, the volume, quality and completeness of the technical documentation, number nonconformities raised and rounds of reviews needed. These factors should be sufficiently clear for manufacturers to be able to estimate the approximate fee.

[3] Range of expected fee to be paid: A minimum to maximum fee charged for the conformity assessment item. In special cases the fee can be different from the upper and lower limits indicated. For "flat fees" only to be filled if applicable.

[4] In case rates may differ for onsite and offsite assessments or because of any other factors, these different rates should be shown. In cases fees differ for different types of assessments these should be shown separately.

[5] If applicable, fees charged by the notified body for conducting consultations with the relevant authorities (e.g. EMA, National Competent Authorities) in addition to fees payable to the relevant competent authority being consulted.

[6] Notified bodies should give an indication on their policy how SMEs are taken into consideration when setting the fee for these companies.

List of Standard Fees for Conformity Assessments Activities under the IVDR (2017/746), Notified body XXXX (NB No)

	Type of Fee[vi]	Fee in local currency	Factors influencing the calculation of fee charged [2]	Fee range (min-max) [3]
Administrative charges				
• Application fee	Flat Hourly Daily			
• Administrative fee related to changes	Flat Hourly Daily			
• Annual certificate maintenance fee (please give details of activities covered)	Flat Hourly Daily			
• Other (specify)	Flat Hourly Daily			
Travel timecosts (excluding expenses such as hotel costs)	Flat Hourly Daily			
Administrative costs related to handling of external services (laboratories, consultation or travel expenses)	Flat Hourly Daily			
Auditing				
• Audit (Certification; Recertification; Surveillance; Subcontractor/Supplier)	Flat Hourly Daily			
• Unannounced Audit	Flat Hourly Daily			
Product testing				
• Laboratory testing for verification of performance (including preparation and reporting but excluding expenditures incurred for external tests)	Flat Hourly Daily			
• Batch testing	Flat Hourly Daily			
Documentation Review /Consultation				
• Technical documentation assessment[4]	Flat Hourly Daily			
• Performance Evaluation Assessment Report (PEAR)	Flat Hourly Daily			
• Expert panel consultation[5]	Flat Hourly Daily			
• Validation of the Summary of	Flat Hourly			

	Type of Fee[vi]	Fee in local currency	Factors influencing the calculation of fee charged [2]	Fee range (min-max) [3]
Safety and Performance (SSP)	Daily			
• Consultation of a medicinal product authority for a companion diagnostic[2]	Flat Hourly Daily			
• Consultation of an EU reference laboratory for performance verification[5]	Flat Hourly Daily			
• Consultation of an EU reference laboratory for batch testing[5]	Flat Hourly Daily			
• Evaluation/review of the Periodic Safety Update Report (PSUR)	Flat Hourly Daily			
• Assessment of changes	Flat Hourly Daily			
Reporting (if not covered above)	Flat Hourly Daily			
Special conditions for manufacturers belonging to SME as defined in Recommendation 2003/361/EC[6]				

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[4] In case rates may differ for onsite and offsite assessments or because of any other factors, these different rates should be shown. In cases fees differ for different types of assessments these should be shown separately.

[5] If applicable, fees charged by notified bodies for conducting consultations with the relevant authorities / expert panels / EU reference laboratories, in case notified body charges fees in addition to fees payable to the consulted bodies
[6] Notified bodies should give an indication in their policy as to how the interests of SMEs are taken into consideration when setting the fees for these companies.

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