



Valid from: 02.12.2024

LIST OF STANDARD FEES FOR WORKS RELATED TO CERTIFICATION PROCEDURES FOR MEDICAL DEVICES IN ACCORDANCE WITH REGULATION MDR 2017/745 IN THE NOTIFIED BODY PCBC S.A.

Medical Devices Certification Department (BM)

No.	Assessment stage	Price in PLN (without VAT)							
		Is, Ir, Im		Class IIa		Class IIb		Class III	
		Type of payment	Rate	Type of payment	Rate	Type of payment	Rate	Type of payment	Rate
1.	Formal assessment of the application, preparation of the cost estimate	per hour	480	per hour	720	per hour	1000	per hour	1200
2.	Assessment of technical documentation	per hour	1500	per hour	2500	per hour	2800	per hour	3200
	Total fee for the assessment of technical documentation depending on the risk class of the devices and the quality and structure of the technical documentation - fee for one product, which includes additional fees* and does not take into account any models/types.	15000 - 90000							
3.	Audit – auditoroday (in PL) - certification audit - surveillance audit - re-certification audit - unannounced audit	per hour	1500	per hour	1500	per hour	1500	per hour	1500
4.	Audit – auditoroday (outside PL) - certification audit - surveillance audit - re-certification audit - unannounced audit	per hour	2250	per hour	2250	per hour	2500	per hour	2500
5.	Analysis and evaluation of documentation submitted to JN due to changes	3000 - 15000							



6.	Analysis and evaluation of reports in accordance with Art. 85-86	6000	10000	15000	15000
7.	Fee for issuing the Opinion of the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products	Established by URPLW MiPB			

No.	Additional fees*	Rate
8.	Sterilized device	8000
9.	Device includes software	8000
10.	Active device (safety and compatibility assessment)	8000
11.	Device containing or consisting of a drug substance	10000
12.	Device containing animal tissue	10000
13.	Device containing nanomaterial	8000
14.	Device containing substances that are absorbed or locally dispersed in the human body	10000
15.	Device which is also a machine as defined in Art. 2, second paragraph, point (a) Directive 2006/42/EC of the European Parliament and of the Council (1)	8000
16.	Device with a measuring function	8000
17.	Device containing an in vitro diagnostic device as an integral part	8000
18.	Expert's participation in the PL audit (1 audit day)	8000
19.	Expert's participation in the audit outside PL (1 audit day)	10000

The number of submitted versions/models/types of the product and the language of the documentation sent for evaluation have an impact on the final version of the offer.

The prices for the audit in the price list do not include travel and accommodation costs.

All fees are given in Polish zlotys (PLN). In the case of offers prepared in other currencies, the amounts are converted according to the average exchange rates of foreign currencies published on the website of the National Bank of Poland on the day of preparing the offer.