



**LIST OF SANDARD FEES FOR WORKS RELATED TO CONFORMITY ASSESSMENT 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	Fee	Type of payment	Fee	Type of payment	Fee	Type of payment	Fee
1.	Formal assessment of the application and documentation	per hour	<b>480</b>	per hour	<b>675</b>	per hour	<b>900</b>	per hour	<b>1000</b>
2.	Assessment of technical documentation	per hour	<b>1500</b>	per hour	<b>2400</b>	per hour	<b>2700</b>	hourly	<b>3000</b>
3.	Audit – auditoroday (in PL) - certification audit - surveillance audit - re-certification audit - unannounced audit	per hour	<b>1200</b>	per hour	<b>1200</b>	per hour	<b>1200</b>	per hour	<b>1200</b>
4.	Audit – auditoroday (outside PL) - certification audit - surveillance audit - re-certification audit - unannounced audit	per hour	<b>1600</b>	per hour	<b>1600</b>	per hour	<b>1800</b>	per hour	<b>1800</b>

5.	Analysis and evaluation of documentation submitted to JN due to changes	<b>3000 - 9000</b>			
6.	Analysis and evaluation of reports in accordance with Art. 85-86	<b>6000</b>	<b>10000</b>	<b>15000</b>	<b>15000</b>
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			

<b>No.</b>	<b>Additional fees</b>	<b>Rate</b>
8.	Sterilized device	<b>8000</b>
9.	Device includes software	<b>8000</b>
10.	Active device (safety and compatibility assessment)	<b>8000</b>
11.	Device containing or consisting of a drug substance	<b>10000</b>
12.	Device containing animal tissue	<b>10000</b>
13.	Device containing nanomaterial	<b>8000</b>
14.	Expert's participation in the PL audit (cost of 1 audit hour)	<b>800</b>
15.	Expert's participation in the audit outside PL (cost of 1 audit hour)	<b>1000</b>

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.