

Pursuant to the Article 13 paragraph 3 of the Law on medical devices („Official Gazette of Montenegro“, No 24/19), the Steering Committee of the Institute for Medicines and Medical Devices, on the session held on 27 January 2022, passed the

DECISION

ON THE AMOUNT AND PAYMENT METHOD OF THE FEES INCURRED BY THE PERFORMANCE OF EXPERT TASKS IN THE AREA OF MEDICAL DEVICES

("Official Gazette of Montenegro ", No 35/23 from 23 March 2023)

Article 1

This Decision shall determine the amount and payment method of the fees incurred by the performance of tasks referred to in the Article 12 paragraph 1 items 1 to 6 and annual fee referred to in the Article 13 paragraph 2 of the Law on medical devices (hereinafter: Law).

Article 2

Amount and payment method of the fees incurred by the performance of tasks referred to in the Article 12 paragraph 1 items 1 to 6 of the Law shall be determined as follows:

No	Type of the task	Amount (EUR)
1.	Maintaining (entry, removal, keeping) the Register of manufacturers and legal persons that carry out wholesale, import and export of medical devices, as well as the Register of specialised retail stores	
	1.1. Entry in the register:	
	Manufacturers of medical devices that:	
	a) have a seat/residence in Montenegro	2000
	b) do not have a seat/residence in Montenegro	70
	Legal persons that carry out wholesale	1500
	Legal/natural persons that carry out import and export of medical devices	400
	Specialised retail stores	1000
	1.2. Amendments to the entry in the Register:	
	Manufacturers of medical devices that :	
	a) have a seat/residence in Montenegro in case that:	
	- control over the fulfillment of conditions for manufacturing is conducted	400
	- control over the fulfillment of conditions for manufacturing is not conducted	200
	b) do not have a seat/residence in Montenegro	50

	<p>Legal persons that carry out wholesale in case that:</p> <ul style="list-style-type: none"> - control over the fulfillment of conditions for manufacturing is conducted - control over the fulfillment of conditions for manufacturing is not conducted 	<p>400</p> <p>200</p>
	Legal/natural persons that carry out import and export of medical devices	150
	<p>Specialised retail stores in case that:</p> <ul style="list-style-type: none"> - control over the fulfillment of conditions for the retail sale is conducted - control over the fulfillment of conditions for the retail sale is not conducted 	<p>400</p> <p>200</p>
	1.3. Removal from the Register:	
	<p>Manufacturers of medical devices that:</p> <p>a) have a seat/residence in Montenegro:</p> <ul style="list-style-type: none"> - at the request of the applicant - based on the decision of the Institute for medicines and medical devices <p>b) do not have a seat/residence in Montenegro</p>	<p>150</p> <p>300</p> <p>50</p>
	<p>Legal persons that carry out wholesale:</p> <ul style="list-style-type: none"> - at the request of the applicant - based on the decision of the Institute for medicines and medical devices 	<p>150</p> <p>300</p>
	Legal/natural persons that carry out import and export of medical devices	150
	<p>Specialised retail stores:</p> <ul style="list-style-type: none"> - at the request of the applicant - based on the decision of the Institute for medicines and medical devices 	<p>150</p> <p>300</p>
2.	2.1. Entry in the Register of medical devices that may be marketed in Montenegro:	
	<p>Medical devices of class I</p> <ul style="list-style-type: none"> - up to 25 products - from 26 to 100 products - over 100 products 	<p>100</p> <p>80</p> <p>60</p>
	<p>Medical devices of class IIa:</p> <ul style="list-style-type: none"> - up to 25 products - from 26 to 100 products 	<p>200</p> <p>180</p>

	- over 100 products	150
	Medical devices of class IIb:	
	- up to 25 products	300
	- from 26 to 100 products	250
	- over 100 products	200
	Medical devices of class III:	
	- up to 15 products	400
	- over 15 products	350
	IN VITRO diagnostic medical devices:	
	- up to 25 products	100
	- from 26 to 100 products	80
	- over 100 products	60
	Active implantable medical devices and apparatus that belong to medical devices of class I, IIa, IIb and III, as well as apparatus for in vitro categories of medical devices:	
	- up to 10 products	450
	- from 11 to 25 products	400
	- over 25 products	350
	Medical devices that do not have document of conformity issued by the manufacturer seated in the European Union, i.e. by the conformity body notified by the European Commission:	
	- medical devices of class I	200
	- medical devices of class IIa	500
	- medical devices of class IIb	500
	- medical devices of class III	600
	- active implantable medical devices and apparatus that belong to medical devices of class I, IIa, IIb and III, as well as apparatus for in vitro categories of medical devices	600
	- IN VITRO diagnostic medical devices	200
	2.2. Extension of the registration of medical devices that may be marketed in Montenegro	Fees for extending the registration of medical devices, per medical device, shall amount to 50%

		of the price determined for the procedure of entry the medical device in question in the Register.
	2.3. Amendments to the entry in the Register of medical devices that may be marketed in Montenegro	75
	2.4. Removal from the Register of medical devices that may be marketed in Montenegro	50
3.	Issuance of import authorisation for medical devices that are not registered (referred to in the Article 66 of the Law): <ul style="list-style-type: none"> - up to 5 medical devices - from 6 to 10 medical devices - from 11 to 15 medical devices - from 16 to 20 medical devices - over 20 medical devices 	60 100 150 200 250
4.	Issuance of the approval for conducting clinical investigations of medical devices: <ul style="list-style-type: none"> - notification on the commencement of a clinical investigation of a medical device - amendment to the notification for a clinical investigation of a medical device 	200 125
5.	Implementation of the vigilance system (per decision) <ul style="list-style-type: none"> - medical devices of class I - IN VITRO diagnostic medical devices - medical devices of class IIa - medical devices of class IIb - medical devices of class III - active implantable medical devices 	10 10 20 30 40 45
6.	Deciding on the following: <ul style="list-style-type: none"> - classification of medical devices with regard to a combination of a medicine and a medical device - classification of a medical device and a consumer good - classification of medical devices 	150 150 300
7.	Issuance of expert opinions from the range of competences of the Institute for medicines and medical devices	100

Article 3

Amount of annual fees referred to in the Article 13 paragraph 2 of the Law shall be determined as follows:

No	Type of the task	Amount (EUR)
1.	Issuance of a Decision on entry in the register of medical devices	25
2.	Issuance of a Decision on entry in the register of manufacturers of medical devices	100
3.	Issuance of a Decision on entry in the register of legal persons that carry out wholesale	100
4.	Issuance of a Decision on entry in the register of legal persons that carry out retail sale	80
5.	Issuance of a Decision on entry in the register of importers of medical devices	100

Article 4

Applicant is obliged to pay a determined fee to the account of the Institute of medicines and medical devices (hereinafter: Institute) within 30 days from the date of receipt of the invoice by the Institute.

Article 5

If the applicant notifies the Institute in writing on withdrawal of the application within seven days from the date of submission of the application, the amount of the fee minus 30% of the paid amount will be returned.

If the applicant notifies the Institute in writing on withdrawal of the application after the expiration of the deadline referred to in paragraph 1 of this Article, it shall bear the fee in the amount determined by this Decision.

Article 6

Decision on the payment method and fees for entering, removing and keeping the register of medical devices, manufacturers and legal entities that perform marketing and import of medical devices ("Official Gazette of Montenegro" No 78/2009) shall cease to have effect when this Decision enters into force.

Article 7

This Decision shall enter into force on the eighth day from the day of its publication in the "Official Gazette of Montenegro", and after obtaining the consent of the Government of Montenegro.

No: 3020/22/430/4-8614

Podgorica, 27 December 2022

President of the Steering Committee

Dr subspec. Vasilije Đurašković