

# Law on Medical Devices

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## I GENERAL PROVISIONS

### Article 1

Manufacturing and distribution of medical devices for human use and for veterinary use is exercised in the manner and under the conditions laid down by this Law.

### Article 2

Medical devices are instruments, apparatuses, devices, or products applied on people and animals, in line with the purpose defined by the manufacturer, which do not achieve their principal action by pharmacological, chemical, immunological, or metabolic means.

Medical devices can be used alone or in combination, including software necessary for the appropriate application, for the following:

- Diagnosis, prevention, monitoring, treatment, or alleviation of disease;
- Diagnosis, monitoring, treatment, alleviation of an injury or disability;
- Investigation, replacement, or modification of the anatomy or of a physiological process;
- Control of conception.

Medical devices, within the meaning assigned by Para 1 of this Article, are also considered to be:

1) Diagnostic medical device "in vitro" which includes any reagent, reagent product, calibrator, control material kit, instrument, apparatus, equipment or system intended for use for the examination in the in vitro conditions, including blood and tissue donations for the transplantation, derived from the human body, for the purpose of providing information:

- Concerning a physiological or pathological state, or
  - Concerning a congenital abnormality, or
  - To determine the safety and compatibility with potential recipients, or
  - To monitor therapeutic measures;
- 2) Product intended to enable its use in combination with the medical device;
- 3) Custom made medical device, manufactured in compliance with a written instruction of a competent expert, with specific structural features;
- 4) Medical device intended for clinical testing.

### Article 3

Manufacturing and distribution of medical devices is of public interest.

Manufacturing and distribution of medical devices can be performed by legal persons and entrepreneurs who fulfil the conditions laid down by this law and by the provisions passed for the implementation of this Law.

### Article 4

The distribution of medical device is prohibited if:

- 1) It does not meet general and specific requirements laid down by the technical regulation;
- 2) It is not in compliance with the statutory general and specific requirements, laid down by this Law;
- 3) Compliance document expired;
- 4) It is not marked in compliance with this Law.

### Article 5

Expressions used in this Law have the following meanings:

1) **Medical device supplier** is a legal person or entrepreneur responsible for the product or service, who meets the conditions to establish a quality assurance system, and can be a manufacturer established in the Republic of Montenegro (hereinafter: Montenegro), or its respective representative or agent established in Montenegro, or importer, or some other respective legal person or entrepreneur placing the medical device on the market or facilitating its use;

2) **Compliance document** is an examination report, declaration of conformity, certificate, or other compliance document confirming the compliance of the medical device with the statutory general and specific requirements;

3) **Declaration of conformity of the medical device** is a declaration by which the supplier guarantees that the product, procedure, or service complies with the statutory requirements;

4) **Accredited legal person for determining compliance** is an independent laboratory, certification body, controlling body, or other respective legal person participating in the procedure of certification, investigation, determination, and control of the compliance of the medical devices with the statutory general and specific requirements;

5) **Technical regulation** is a regulation which determines characteristics of the medical device or the manufacturing procedure and manner, symbols, packaging, labelling, and terminology related to it, or it refers to appropriate standards (EN ISO standards or equally strict standards of other countries);

6) **Requirement** implies the criteria which must be satisfied by the medical device in compliance with the technical regulation;

7) **Manufacturer** is a legal person or entrepreneur which produces the medical devices;

8) **Good clinical practice (GCP)** represents a quality assurance system in planning and implementing clinical testing for obtaining valid clinical conclusions with the protection of participants in the clinical testing;

9) **Clinical testing ordering party** is a natural or legal person undertaking responsibility for launching, managing, or financing the clinical testing;

10) **Medical device side effects** is any detrimental, or inappropriate effect of the medical device, any deviation from the characteristics and/or effects of the medical device which is not in compliance with label and instruction for use, and which can, directly or indirectly, cause death or serious health problems of the patient, or respective user and safety of other persons;

11) **Serious side effects of the medical device** is any detrimental, or inappropriate effect of the medical device, any deviation from the characteristics and/or effects of the medical device which is not in compliance with label and instruction for use, and which has, directly or indirectly, caused death, immediate life threat, hospital care, or respective prolongation of the hospital care of the patient, as well as other users and other persons, if there had been no need for that before the use of the medical device;

12) **Specialised shop** is a retail facility for the retail of the medical devices;

13) **Medical device advertising** is any form of providing information about the medical device by the manufacturer, or the sponsorship of the manufacturer, or the holder of the permit for placing the medication on-market, to foster prescribing of the medical devices, their supplying, sale, and consumption.

## II COMPETENCIES

### Article 6

Ministry competent for health and ministry competent for veterinary (hereinafter: competent ministry), in compliance with this Law:

1) passes the regulations for the implementation of this Law;

2) Gives consent to the document on the establishment of committees and the list of experts;

3) stipulates the content and manner of keeping the register of the: accredited legal persons for determining the compliance; manufacturer, legal persons and entrepreneurs engaged in the wholesale, import and export of the medical devices, specialised shops, as well as medical devices;

4) Decides appeals in the second instance procedure;

5) Performs other jobs in compliance with the law.

### Article 7

Administrative authority competent for medications and medical devices (hereinafter: competent administrative authority) performs administrative and related professional jobs concerning medical devices as follows:

1) Issues a decision on accreditation of the legal persons for determining the compliance of the medical devices, issues a decision on revocation of accreditation, and keeps the register of the accredited legal persons for determining the compliance;

2) Enters in or removes from the register, and keeps the register of the manufacturers, legal persons, and entrepreneurs which are engaged in the wholesale, import and export of the medical devices, as well as specialised shops;

3) Enters in or removes from the register, and keeps the register of the medical devices which can be distributed in Montenegro;

- 4) Makes records of clinical testing of the medical devices and, as necessary, gives consent for the beginning clinical testing;
  - 5) Evaluates the relation between risk and benefit of the medical devices based on the monitoring of the side effects;
  - 6) Decides on the medical device classification where there is combination of the medication and the medical device or the medical device and general purpose object;
  - 7) Performs inspection over the accredited legal persons for determining the compliance of the medical devices; over the manufacturers and legal persons and entrepreneurs performing distribution in compliance with the law
  - 8) Prohibits distribution, or orders the suspension of the distribution or withdrawal from the distribution of the medical devices not meeting the statutory general and specific requirements;
  - 9) Cooperates with international subjects and national regulatory bodies in the field of medical devices;
  - 10) Performs other jobs in compliance with the law.
- A decision on the entry into or removal from the register from Para 1, Point 2 and 3 of this Article, is issued by the competent administrative authority.

#### **Article 8**

In the process of passing documents from the Article 7, Para 1, Points 1, 2, 3, 6 and 8 of this Law, the provisions of the law regulating general administrative procedure shall apply, unless stipulated otherwise by this Law.

Against the document of the competent administrative authority from Para 1 of this Article, a representation can be made to the competent ministry.

Against the decision of the competent ministry from Para 2 of this Article, administrative dispute can be instituted.

#### **Article 9**

The costs made while performing professional jobs when issuing decisions from the Article 7, Para 1, Points 1, 2, 3 and 6 of this Article are incurred by the person submitting the request, or application, unless stipulated otherwise by this Law.

Method of payment and amount of the fee from Para 1 of this Article, based on the real costs of the jobs performed, are determined by the competent ministry.

The fees from Para 1 of this Article, are the revenue of the Republic of Montenegro budget, and shall be reallocated for the financing of jobs from Para 1 of this Article.

#### **Article 10**

For performing some professional and advisory jobs while issuing a decision on the accreditation of the legal persons for determining the compliance and decision making on the medical device classification, as well as professional jobs from the Article 7 of this Law, which require special expert knowledge in medicine, dentistry, pharmacy, veterinary, or other related fields, or respective technical fields related to the production of the medical devices, the competent administrative authority, with the consent of the competent ministry, establishes committees, or the list of experts comprised of experts in these fields.

The committee members and the experts from the list of experts from Para 1 of this Article, are entitled to the compensation for their work, in compliance with the general enactment of the competent ministry.

#### **Article 11**

The senior and the employees in the competent administrative authority cannot perform, on their own behalf for their own account, as well as on the behalf and for the account of another legal and natural person, jobs of design, production, and distribution of the medical devices, nor can they have other personal interest (ownership, shares, membership in the management or contractual relationship) with the persons engaged in these activities, for which they shall sign a statement.

The persons from Para 1 of this Article, as well as the committee members and the experts from the list of experts, cannot represent legal and natural persons related to the production and distribution of the medical devices, for which they shall sign a statement.

### **III MEDICAL DEVICE CLASSIFICATION**

#### **Article 12**

Medical devices are divided:

- 1) According to the level of risk to the user:

- Class I-medical devices with a low risk for users;
  - Class IIa-medical devices with a higher risk for users;
  - Class IIb-medical devices with a high risk for users;
  - Class III-medical devices with the highest risk for users;
- 2) According to the nature of the product, connection to energy sources and other characteristics to:
- Non-invasive;
  - Invasive;
  - Active;
- 3) According to the duration of the application in or on humans, or animals to:
- Transient application (intended for continuous use for less than 60 minutes);
  - Short-term application (y intended for continuous use for not more than 30 days);
  - Long-term application (intended for continuous use for more than 30 days).
- Qualifiable terms and the method of classification of some types of the medical device are stipulated by the competent ministry.

#### **Article 13**

In the event of combination of a medication and medical device, or the medical device and general purpose object, the classification is performed according to the principal purpose declared by the manufacturer.

If the classification from Para 2 of this Article is disputable, competent administrative authority decides on the classification.

#### **Article 14**

Medical devices, depending on their purpose and the level of risk to the user, can be:

- 1) Used exclusively in performing health or veterinary activity;
- 2) Dispensed, or sold in pharmacies, or veterinary pharmacies as either prescription or non-prescription;
- 3) Dispensed, or sold in specialised shops;
- 4) Sold over the counter.

The dispensing and prescription method of the medical devices is stipulated by the competent ministry.

### **IV REQUIREMENTS WHICH MUST BE MET BY MEDICAL DEVICES**

#### **Article 15**

In Montenegro, only medical devices meeting statutory general and specific requirements can be distributed.

#### **Article 16**

General requirements, within the meaning assigned by the Article 15 of this Law, are:

- 1) Medical devices should be designed and manufactured in such a way that, when used, embedded, and maintained under the conditions and for the purposes intended they will not compromise the health or the safety of users;
- 2) Medical device manufacturing ensured application of the quality assurance system foreseen for the design and production of the medical device.

Specific requirements are related to the purpose of the medical device.

Specific requirements and the qualifiable content of the general requirements from Para 1 and 2 of this Article are stipulated by the competent ministry.

### **V PROCEDURE OF DETERMINING COMPLIANCE AND LABELLING OF THE MEDICAL DEVICE**

#### **Article 17**

Procedure of determining compliance is a procedure where, directly or indirectly, it is determined whether medical device meets the requirements from the Article 16 of this Law.

#### **Article 18**

Procedure of determining compliance of the medical device with the requirements from the Article 16 of this Law depends on the medical device classification according to the level of risk to the user:

- 1) For Class I medical device, manufacturer by himself determines the compliance of his product with the statutory requirements and provides a declaration on conformity on his own responsibility except for the sterile products of Class I and products with a determined measurement scale being treated as medical devices of a higher class;

2) For Class IIa, Class IIb, and Class III medical device, the compliance with the statutory requirements is determined and the control of the quality assurance system is performed by the accredited legal person for determining compliance (hereinafter: accredited legal person).

In the event from Para 1, Point 2 of this Article, the accredited legal person shall issue an appropriate compliance document.

Procedure of determining compliance from Para 1 of this Article is qualifiably stipulated by the competent ministry.

### **Article 19**

Jobs of determining the compliance of the medical device with the general and specific requirements and of the assurance quality system control is performed by the legal person from the Article 18, Para 1, Point 2 of this Law, by virtue of decision on accreditation.

Legal person can be accredited for performing jobs from Para 1 of this Article, if it meets organisational, personnel, technical and other conditions.

Decision on accreditation includes:

- 1) Field of work for which the accreditation is issued;
- 2) Type and range of authorisation in the procedure of determining the compliance, or the procedure of the assurance quality system control.

Decision on accreditation is issued for an indefinite period.

Qualifiable content of conditions from Para 2 of this Article are stipulated by the competent ministry.

### **Article 20**

Accredited legal person from the Article 19 of this Law assumes full responsibility for the medical device whose compliance it determines.

### **Article 21**

The responsible person and employees in the accredited legal person cannot have commercial or any other interest in relation to the medical device whose compliance it determines.

Notwithstanding, if, due to inaccessibility of infrastructure, technology, and other objective reasons, only one legal person is accredited for determining the medical device compliance, jobs on determining the compliance can be performed by the persons from Para 1 of this Article, under the conditions stipulated by the competent ministry.

Persons from Para 1 and 2 of this Article are obliged to keep the data and information available in the procedure of determining the medical device compliance as a business secret.

### **Article 22**

Any legal person can make a representation to the competent administrative body against the conduct of the accredited legal person.

### **Article 23**

Accredited legal persons are obliged to inform, without delay, the competent administrative authority about the changes related to the conditions under which the accreditation was obtained.

Competent administrative authority can issue a decision on the revocation of accreditation, if it determines that the accredited legal person:

- 1) Ceased to meet the conditions from the Article 19, Para 2 of this Law;
- 2) Issues the declarations of conformity contrary to the provisions of this Law.

In the event from Para 2 of this Article, accredited legal person is removed from the register of the accredited legal persons.

### **Article 24**

Compliance of the medical device with the statutory requirements is confirmed with the compliance document.

The compliance document is valid five years from the date of issuance.

The content of the compliance document is stipulated by the competent ministry.

### **Article 25**

Costs on determining the compliance are incurred by the applicant for the evaluation of the compliance, paying the fee whose amount, and method of payment are determined by the accredited legal persons, with a consent of the competent administrative body.

### **Article 26**

Medical device is labelled by a statutory compliance label in accordance with the compliance document.

Notwithstanding the Para 1 of this Article, medical device intended to the clinical testing or is custom made for a certain user need not be labelled with statutory label.

The content of the compliance label and the method of the medical device labelling from Para 1 of this Article is stipulated by the competent ministry.

#### **Article 27**

Competent administrative authority, in the procedure of entering in the register, admits all of the compliance documents and compliance labels of the medical device issued in compliance with EN ISO standards or equally strict standards of other countries.

#### **Article 28**

Medical device must have the instructions for use written in the language officially used in Montenegro and prepared in a user friendly manner.

The content of the instructions from Para 1 of this Article is stipulated by the competent ministry.

### **VI MANUFACTURING, DISTRIBUTION, AND ADVERTISING OF MEDICAL DEVICE**

#### **1. Medical device manufacturing**

##### **Article 29**

Manufacturing of the medical devices includes design, manufacturing, packaging and labelling, quality assurance system, storage and distribution of the medical devices.

Manufacturing of the medical device also includes sale of these products to the legal persons engaged in the wholesale of the medical devices.

##### **Article 30**

Manufacturers are obliged to register their activity in compliance with the general regulations on company registration.

Manufacturers must have a person responsible for monitoring harmful side effects and undertaking measures in the event of accidents and, if necessary, meet other conditions, as well, for performing the medical device manufacturing, especially those ensuring protection of citizens' health.

Qualifiable terms from Para 2 of this Article are stipulated by the competent ministry.

##### **Article 31**

Medical device manufacturing can be performed only by the legal persons and entrepreneurs entered in the register, in compliance with this Law.

The entry in the register is performed upon the application containing:

- 1) Name and address of the manufacturer and place of manufacturing;
- 2) List of the medical devices;
- 3) Description of the manufacturing procedure of the medical device manufactured;
- 4) Other information in compliance with the conditions from the Article 30 of this Law.

Qualifiable content of the documentation from Para 2 of this Article is stipulated by the competent ministry.

##### **Article 32**

Manufacturer is obliged to ensure the compliance document for the products it manufactures in compliance with the provision of the Article 18 of this Law.

##### **Article 33**

Manufacturer is obliged to apply the technical regulations during the medical device manufacturing, or during its quality assurance.

Technical regulation can stipulate that it assumes the medical device meets the requirements of the optional standards the technical regulation refers to.

##### **Article 34**

Manufacturer is obliged to inform the competent administrative authority and the accredited legal person about all the changes concerning the manufacturing.

If the manufacturer is not established in Montenegro, the obligation from Para 1 of this Article falls to the medical device supplier.

##### **Article 35**

Removal of the manufacturer from the register is performed:

- 1) Upon the request of the manufacturer;
- 2) If the competent administrative authority establishes that the manufacturer no longer meets the statutory conditions.

### **Article 36**

Manufacturer is responsible for the manufacturing and placing the medical device on-market.

Manufacturer which is not established in Montenegro can place its products on-market in Montenegro through a representative, importer, or other legal person or entrepreneur, if they are established in Montenegro.

### **Article 37**

Persons from the Article 36 of this Law can place on-market only those medical devices which are entered in the register in compliance with this Law.

The entry in the register is performed upon the application submitted by the persons from the Article 36 of this Law.

The application from Para 2 of this Article contain: name and place of the manufacturer, list of the medical devices, and other necessary documentation, in compliance with the Art. 31 and 32 of this Law.

The Applicant is responsible for the documentation from Para 3 of this Article.

The persons from the Article 36 of this Law are responsible for the damage which can occur by the use of the medical device, and are obliged to submit the proof on the insurance from the consequences of the use of the medical device to the competent body.

Qualifiable content of the documentation from Para 3 of this Article is stipulated by the competent ministry.

### **Article 38**

When it establishes that the medical device does not meet the statutory general and special requirements in compliance with this Law, the competent administrative authority prohibits the distribution, or orders the suspension of distribution, or withdrawal from the distribution of the medical device.

In the event from Para 1 of this Article, the medical device is removed from the register of the medical devices.

## **2. Medical device distribution**

### **Article 39**

Medical device distribution includes wholesale, import and export, and retail.

The medical device wholesale implies procurement, storage, and delivery of the medical devices, except the dispensing of the medical devices to individuals.

### **Article 40**

Legal persons and entrepreneurs engaged in wholesale, and import and export of the medical devices are obliged to register their activity in compliance with the general regulations on the registration of the companies.

The persons from Para 1 of this Article must have a person responsible for monitoring harmful side effects and undertaking measures in the event of accidents and, if necessary, meet other conditions, as well, for performing the activities of wholesale, or import and export of the medical devices, especially those ensuring protection of citizens' health.

Qualifiable terms from Para 2 of this Article are stipulated by the competent ministry.

### **Article 41**

The medical device retail is performed by the pharmacy, veterinary pharmacy, specialised shop, and other legal person and entrepreneur, in compliance with the regulation from the Article 14, Para 2 of this Law.

Specialised shop is obliged to register its activity of the medical device retail in compliance with the general regulations on the registration of the companies.

Specialised shop must meet other necessary conditions as well qualifiably stipulated by the competent ministry.

### **Article 42**

The persons from the Art. 40 and 41 of this Law can be engaged in the medical device distribution only if they are entered in the register, in compliance with this Law.

The persons from Para 1 of this Article shall submit, to the competent administrative body, application and other necessary documentation in compliance with the statutory requirements for performing the activity.

Qualifiable content of the documentation from Para 2 of this Article is stipulated by the competent ministry.

#### **Article 43**

The provisions of the article 35 of this Law are applied to the removal of persons engaged in the medical device distribution from the register.

#### **Article 44**

Legal and natural persons which, in performing their activity, get, in any way, into the possession of a medical device (carrier, the postal operator, owner of the customs warehouse, etc.), are obliged to act in compliance with the instruction displayed on the package of the medical device for transport.

### **3. Medical device advertising**

#### **Article 45**

It is prohibited to advertise medical devices from the Article 14, Para 1, Point 1 of this Law.

Notwithstanding, competent administrative authority can allow advertisings of the medical devices which are not classified as a high level of risk.

Qualifiable terms and method of the medical device advertising from Para 2 of this Article are stipulated by the competent ministry.

## **VII CLINICAL TESTING**

#### **Article 46**

Clinical testing of the medical device is determining or confirming its safety and efficiency in compliance with the intended purpose determined by the manufacturer.

#### **Article 47**

Manufacturer of the medical device being tested, or the respective ordering party of the clinical testing, prior to the medical device testing, is obliged to ensure the persons subjected to the testing in the event of the occurrence of damage in the course of the clinical testing, in compliance with the Law.

The persons from Para 1 of this Article must, prior to the medical device clinical testing in the veterinary medicine, specify, in the contract, the amount of fee to the owner of the animal in the event of the occurrence of damage caused by the clinical testing.

#### **Article 48**

The persons from the Article 47, Para 1 of this Law are obliged to inform the competent administrative authority about implementing the clinical testing of the medical devices of classes IIa, IIb and III by submitting an application.

The Applicant from Para 1 of this Article is obliged to enclose with the application the opinion of the ethical committee and other necessary documentation.

Qualifiable content of the documentation from Para 2 of this Article, as well as the content and method of keeping the records of the clinical testing, are stipulated by the competent ministry.

#### **Article 49**

The Applicant from the Article 48 of this Law cannot begin with the clinical testing prior to the expiry of 60 days from the date of the application.

Notwithstanding, competent administrative authority may give consent the clinical testing begins before the expiry of the period from Para 1 of this Article.

The procedure of the clinical testing is qualifiably stipulated by the competent ministry.

#### **Article 50**

If there should appear a serious side effect, accident or other unexpected event during the clinical testing of the medical device, the Applicant from the Article 48 of this Law is obliged to immediately inform the competent administrative authority and the ethical committee of the health, or veterinary institution.

In the event from Para 1 of this Article, the competent administrative authority can suspend or prohibit the clinical testing of the medical device based on the evaluation of the relation between the risk and benefit.

## **VIII MONITORING THE SIDE EFFECT OF THE MEDICAL DEVICES**

#### **Article 51**

Side effects of the medical devices are monitored by the health institution appointed with a special act by the competent ministry.

For performing jobs from Para 1 of this Article, the health institution must also meet special requirements in terms of personnel, space and equipment, which are stipulated by the competent ministry.

#### **Article 52**

Medical device supplier, and any other legal and natural person, who in his work determines or suspects hitherto unknown side effects of the medical device is obliged to inform the health institution from the Article 51 of this Law about that.

If the person from Para 1 of this Article determines in its work serious side effects of the medical device, it also informs the competent administrative authority about that.

The competent administrative authority follows the information from Para 1 of this Article to make it available to the health and veterinary workers, and to the general public as necessary.

In the event from Para 2 of this Article, the competent administrative authority orders the suspension of distribution or withdrawal from distribution of the medical device.

#### **Article 53**

Competent administrative authority cooperates with the authorised centre for adverse events of the World Health Organization, other agencies and institutions for obtaining the latest professional information about the safe use of the medical device.

#### **Article 54**

The method of collecting information and the method of monitoring side effects and serious side effects of the medical devices are qualifiably stipulated by the competent ministry.

### **IX INSPECTION**

#### **Article 55**

Inspection of the medical devices is performed by the competent administrative authority.

The jobs of inspection from Para 1 of this Article are performed by the medical device inspectors, in compliance with the law.

#### **Article 56**

Medical device inspectors perform the inspection especially with regards to:

- Compliance documents, technical documentation and labelling of the medical devices;
- Implementing appropriate examinations and testing of the medical devices which are on-market or in use, regarding their compliance with the statutory requirements;
- Medical device advertising.

In addition to the administrative measures stipulated by the law regulating the inspection, when they determine that there was a breach of the law and other regulations, inspectors from Para 1 of this Article may temporarily prohibit the accredited legal person to perform jobs for which it is accredited, if they determine that it does not meet the statutory conditions for performing such jobs, or if they determine certain irregularities in its work, as well as to file a motion for revoking the accreditation, if the accredited legal person does not remove the irregularities determined.

### **X PUNITIVE PROVISIONS**

#### **Article 57**

A fine ranging from two hundred- to three hundred-fold amount of the lowest price of labour in Montenegro shall be imposed to the legal person and entrepreneur for the violation if it:

1) Places on-market, or is engaged in the distribution of the medical device which does not meet general and specific requirements stipulated by the technical regulation, or is not in compliance with the statutory general and specific requirements in compliance with this Law, or the compliance document expired, or is not labelled in compliance with this Law (Article 4);

2) Dispenses, or sells medical devices to the users contrary to the provision of the Article 14 of this Law;

For the violation from Para 1 of this Article, the responsible person in the legal person shall also be imposed a fine ranging from ten to twentyfold amount of the lowest price of labour in Montenegro.

In addition to the fine for the violation from Para 1 of this Article, protective measure of professional ban may be imposed to last from one moth to one year.

#### **Article 58**

A fine ranging from one hundred- to two-hundred-and-fifty-fold amount of the lowest price of labour in Montenegro shall be imposed to the legal person and entrepreneur for the violation if it:

- 1) Without delay, does not inform the competent administrative authority about the changes related to the conditions under which the accreditation was obtained (Article 23);
- 2) Places on-market the medical device which is not labelled by a statutory compliance label in accordance with the compliance document (Article 26);
- 3) Places on-market the medical device which has not the instructions for use in compliance with the provision of the Article 28 of this Law;
- 4) Manufactures the medical devices without registering its activity in compliance with the general regulations on company registration, or does not have a person responsible for monitoring harmful side effects and undertaking measures in the event of accidents, or does not meet other conditions for performing the activity of the medical device manufacturing (Article 30);
- 5) Is engaged in manufacturing, import, export, or wholesale or retail of the medical devices, without being entered in the register in compliance with this Law (Art. 31 and 42);
- 6) Does not ensure the compliance document for the medical devices it manufactures (Article 32);
- 7) Does not apply the technical regulations during the medical device manufacturing, or during its quality assurance (Article 33);
- 8) Does not inform the competent administrative authority and the accredited legal person about all the changes concerning the manufacturing (Article 34);
- 9) Places on-market such medical device which is not entered in the register in compliance with this Law (Article 37 Para 1);
- 10) Is engaged in wholesale, or import and export of the medical devices without registering its activity in compliance with the general regulations on the registration of the companies, or does not have a person responsible for monitoring harmful side effects and undertaking measures in the event of accidents, or does not meet other conditions for performing the activities of wholesale of the medical devices (Article 40);
- 11) Is engaged in retail of the medical devices without registering its activity in compliance with the general regulations on the registration of the companies, or does not meet other statutory conditions (Article 41, Para 2 and 3).

For the violation from Para 1 of this Article, the responsible person in the legal person shall also be imposed a fine ranging from five- to fifteen-fold amount of the lowest price of labour in Montenegro.

In addition to the fine for the violation from Para 1 of this Article, protective measure of professional ban may be imposed to last from one month to one year.

#### **Article 59**

A fine ranging from fifty- to two hundred-fold amount of the lowest price of labour in Montenegro shall be imposed to the legal person and entrepreneur for the violation if it:

- 1) Advertises medical devices contrary to the provision of the Article 45 of this Law;
- 2) Prior to the clinical testing of the medical devices, does not ensure the persons subjected to the testing in the event of the occurrence of damage in the course of the clinical testing, or does not specify, in the contract, the amount of fee to the owner of the animal in the event of the occurrence of damage caused by the clinical testing (Article 47);
- 3) Does not submit an application to the competent administrative body for the implementation of the clinical testing of the medical devices in compliance with the provision of the Article 48 of this Law;
- 4) Begins with the clinical testing prior to the expiry of the period from the Article 49 of this Law;
- 5) Does not inform the health institution monitoring the side effects of the medical devices on the determined hitherto unknown side effects of the medical device; or the competent administrative authority on the serious side effects of the medical device (Article 52, Para 1 and 2).

For the violation from Para 1 of this Article, the responsible person in the legal person shall also be imposed a fine ranging from ten- to twenty-fold amount of the lowest price of labour in Montenegro.

#### **Article 60**

A fine ranging from twenty-fold amount of the lowest price of labour in Montenegro shall be imposed for the violation to:

- 1) The committee members and the experts from the list of experts, if they act contrary to the provision of the Article 11 of this Law;

2) The responsible person and employees in the accredited legal person, if they act contrary to the provision of the Article 21 of this Law.

## **XI TRANSITIONAL AND FINAL PROVISIONS**

### **Article 61**

Regulations for the implementation of this Law shall be passed within six months from the date of entry into force of this Law.

Until passing the regulations from Para 1 of this Article, the regulations passed, in order to implement the law that was in force until the date of entry into force of this Law, shall apply.

### **Article 62**

Manufacturers and the legal persons and entrepreneurs engaged in the distribution of the medical devices are obliged to harmonise their businesses and activities with the provisions of this Law and the provisions passed for the implementation of this Law within two years from the date of entry into force of this Law.

### **Article 63**

Authorisation for placing the medical device on-market, issued based on the regulations that were in force at the time when the authorisation was issued, stays in force until the expiry of the period for which it was issued.

### **Article 64**

The act of determining the health institution which monitors side effects of the medical devices shall be passed within three months from passing the by-law from the Article 51, Para 2 of this Law

### **Article 65**

On the effective date of this Law, the Law on Manufacture and Distribution of Medications ("Official Gazette SRY", no. 18/93, 23/02, 24/94 and 28/96) ceases to be valid in the part concerning medical devices, as well as the provisions of the Article 3, Point 12, of the Article 31, Para 1, 2, 4 and 5, in the part concerning the medical equipment, and the Article 96, Para 2, Point 1, in the part concerning the medical equipment of the Veterinary Law ("Official Gazette of the RM", no. 11/04).

### **Article 66**

This Law shall enter into force on the eighth day of its publication in the "Official Gazette of Republic of Montenegro".