LAW ON MEDICAL DEVICES

I BASIC PROVISIONS

Article 1

This Law regulates the conditions for manufacturing, marketing and use of medical devices for human use (hereinafter: „medical devices"), measures to ensure quality, safety and possibility of intended purpose, technical assessment, conformity assessment of medical devices with the essential requirements, as well as other issues relevant for the performing of this activity.

Article 2

If a medical device incorporates a medicine and they together form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single product shall be governed by the regulations governing medicines.

The provisions of this Law shall apply to the essential requirements regarding the safety and performances of medical devices.

If a medical device incorporates a medicine that may also be used separately and which contributes to the effect of the medical device, that medical device shall be subject to the provisions of this Law, and the medicine shall be subject to the regulations governing medicines.

If a medical device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicine constituent or a medicine derived from human blood or human plasma, in accordance with the regulations governing medicines, and which could act upon the human body with action ancillary to that of the medical device, that medical device shall be subject to the provisions of this Law.

The provisions of this Law shall also apply to *in vitro* diagnostic medical devices made of tissues, cells or other substances of human origin.

The provisions of this Law shall apply to accessories of medical devices.

Article 3

The provisions of this Law shall apply to certain groups of products intended by their manufacturer to be used solely for aesthetic or other non-medical purposes, and which are similar to medical devices in terms of their function and risk level.

Products that have medical and non-medical intended purpose shall comply with a specific law governing this type of product.

Article 4

A medical device in the manufacture of which animal tissues or products of animal origin are used (beef, goat and sheep species, as well as deer, salmon, mink and cats) is a medical device that must meet certain special requirements in terms of the risk of transmission of spongiform encephalopathy (TSE) to patients or other persons under normal conditions of use.

The provisions of this article shall not apply to medical devices which are not intended to be in contact with the human body or which are intended to come into contact solely with clean and undamaged skin.

Article 5

The provisions of this Law shall not apply to:

1) medicines;
2) cosmetic products;
3) human blood, blood products, plasma or blood cells of human origin or products containing blood products, plasma or cells at the time of placing on the market, other than products referred to in Article 2 paragraph 4 of this Law;
4) transplants, tissues, cells of human origin, as well as products containing or originating from tissues or cells of human origin, other than products referred to in Article 2 paragraph 4 of this Law; and
5) transplants, tissues or cells of animal origin, unless the medical device is manufactured or made of non-living animal tissue or a product made of non-living animal tissue.

Article 6

Manufacturing and marketing of medical devices is of public interest.

Manufacturing and marketing of medical devices may be carried out by natural and legal persons fulfilling the requirements prescribed by this Law.

Article 7

Marketing of a medical device shall be prohibited if:

1) it does not comply with the essential requirements, i.e. if it has not undergone conformity assessment in accordance with this Law and the law governing the field of technical requirements for products and conformity assessment;
2) it is not inscribed in the register of medical devices in accordance with this Law;
3) it was manufactured by a legal or natural person which is not inscribed in the register of manufacturers in accordance with this Law;
4) it is placed on the market by a legal or natural person which is not inscribed in the registers maintained by the Agency for Medicines and Medical Devices (hereinafter: ,,the Agency");
5) it does not bear the conformity mark, i.e. it is not labelled in accordance with this Law;
6) it does not have appropriate certificate of conformity;
7) it has passed its expiry date indicated on the packaging or if an malfunction has been established in respect of its prescribed quality;
8) it is a falsified medical device, as well as a medical device for which there is reasonable suspicion that it is falsified;
9) it is not registered in Montenegro and the import of which is not authorized in accordance with Article 67 of this Law;
10) it is manufactured in a healthcare institution in order to be used in that healthcare institution in accordance with this Law; and
11) in other cases in accordance with this Law.

Article 8

The terms used in this law for natural persons in the masculine gender imply the same terms in the feminine gender.

Article 9

The terms used in this Law shall have the following meanings:

1) ,,active implantable medical device" means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain in the body after the procedure;
2) ,,active medical device" means any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity;
3) ,,CAMD" means the association of competent authorities of the European Union Member States for medical devices;
4) ,,medical device defect" means any deficiency in the identity, quality, durability, reliability, safety or performances of a medical device. Medical device deficiencies include malfunction, use errors or inadequate labeling;
5) ,,distributor" (hereinafter: ,,wholesaler") means a legal or natural person with a seat or residence in Montenegro, involved in the supply chain and supplying a medical device in the course of its activity and importer, other than the manufacturer or the authorized representative of the manufacturer;
6) ,,declaration of conformity of a medical device" (hereinafter: ,,declaration of conformity") means a document by which the manufacturer confirms that the medical device complies with the essential requirements;
7) ,,good distribution practice" means a system of quality assessment guidelines related to the organization, implementation and monitoring of distribution of a medical device from the manufacturer to the end user;
8) ,,good clinical practice" means the guidelines for quality assurance standards when planning and conducting clinical investigations to obtain valid clinical findings with the appropriate protection of participants in clinical investigations;
9) ,,reprocessing" means a process carried out on a used medical device in order to allow its safe reuse, including cleaning, disinfection, sterilization and related procedures, as well as testing and restoring the technical and functional safety of the medical device;
10) ,,EUDAMED" means the European databank on medical devices, which centralizes data on registration of manufacturers, or authorized representatives of manufacturers and medical devices placed on the market of the European Union, data on certificates issued, amended, as well as certificates that ceased to be valid, withdrawn or refused, data obtained in accordance with the medical device vigilance procedure and data on clinical investigations;
11) ,,falsified medical device" means any device with a false presentation of its identity or its source or its CE marking certificates or documents relating to CE marking procedures. This definition does not include medical devices with unintentional quality deficiencies (medical device quality defect) and is without prejudice to infringements of intellectual property rights;
12) ,,free sale certificate" means a document proving that the medical device may be marketed in the manufacturer's country or in the market of a member state of the European Economic Area (hereinafter: ,,EEA member state");
13) ,,principal investigator" means a qualified person responsible for conducting a clinical investigation at an investigation site. If a clinical investigation is conducted by a team of individuals at an investigation site, the principal investigator is responsible for the work of the team;

14) ,,generic medical device group" means a set of medical devices having the same or similar intended use or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;
15) ,,designated conformity assessment body" (hereinafter: assessment body) means a legal person designated by the relevant ministry to carry out product conformity assessment, for the manufacturer;
16) ,,implantable medical device" means any medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or to be introduced permanently into a natural orifice, and which is intended to remain in the body after the medical procedure;
17) ,,informed consent of a subject" (hereinafter: ,,informed consent") means an written statement, with the date and the subject's signature, of his willingness to participate in a particular clinical investigation, given by a person capable of giving consent or by a legal representative of a incapacitated person, in accordance with the law, and which is given voluntarily after having been informed fully of the nature, relevance, consequences and health risks;
18) ,,incident" means any malfunction or deterioration in the characteristics or performance of a medical device, as well as any inadequacy in the labelling or in the instructions for use that directly or indirectly led or might have led to the death of a patient, user or other person, or to serious deterioration of his state of health;
19) ,,*in vitro* diagnostic medical device" means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, softver or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:
    - concerning a physiological or pathological state;
    - concerning a congenital physical or mental abnormality;
    - concerning a predisposition for a state of health or illness;
    - to determine the safety and compatibility with potential recipients;
    - to predict response or reaction to treatment;
    - to define or monitor therapeutic measures.

    Specimen receptacles are considered to be *in vitro* diagnostic medical devices. Specimen receptacles are those medical devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination.

    Products for general laboratory use are not *in vitro* diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination;
20) ,,investigator" means a team member at an investigation site appointed and supervised by the principal investigator, conducting key procedures in clinical investigation or taking significant decisions concerning a clinical investigation;
21) ,,supplier" means a manufacturer, manufacturer's authorized representative, wholesaler or importer;
22) ,,medical device conformity document" (hereinafter: ,,conformity document") means: declaration of conformity, investigation report, certificate, certificate of inspection or other document confirming the conformity of the medical device with the essential requirements;

23) ,,Clinical Evaluation Report" means documents on clinical evaluation;
24) ,,Unique Device Identification" (,,UDI") means a unique numeric or alphanumeric code specific to a medical device consisting of two parts:
    - medical device identifier;
    - manufacturing identifier.
    The Unique Device Identification provides access to useful and relevant information concerning a medical device and provides more efficient traceability of a medical device, allows easier withdrawal of a medical device from market, suppresses falsifying and improves patients safety. The Unique Device Identification is not replacement for or addition to the prescribed requirements for medical device labeling;
25) ,,calibrator and control material" means any substance, material or product intended to establish measurement relations or to verify the performance characteristics of a medical device in relation to its intended purpose;
26) ,,medical device category" means a a set of medical devices having common areas of intended use or common technology;
27) ,,medical device categorization" means the procedure for determining the category of the medical device;
28) ,,medical device classification" means the procedure for determining the risk class of a medical device;
29) ,,clinical performance" means the method of work of a medical device or the response of a patient to a medical device in relation to the intended purpose of that medical device, when applied properly to an appropriate patient;
30) ,,clinical safety" means the absence of an unacceptable risk from a medical device when used in accordance with the manufacturer's instructions for use;
31) ,,clinical data" means all information concerning safety and/or performance of a medical device that is generated from the use of a device. Clinical data is sourced from:
    - clinical investigation(s) of the medical device concerned, or
    - scientific literature on clinical investigation(s) or other studies of a similar medical device for which equivalence to the medical device in question can be demonstrated; or
    - published or unpublished reports on other clinical experience of either the medical device in question or a similar medical device for which equivalence to the medical device in question can be demonstrated;
32) ,,critical non-conformity of marketing of a medical device with the good distribution practice guidelines" means non-conformity that has led or might lead to marketing of a medical device that may pose a threat to the life or health of people or to public health;
33) ,,vigilance coordinator" means a healthcare professional employed in a healthcare institution who carries out tasks related to the organization and improvement of the implementation of good practice in collecting and reporting suspicions of incidents and communications on the risks of the use of medical devices in a health institution and who is the contact person of the health institution for vigilance and is working directly with the Agency. The coordinator for vigilance is appointed by the health institution and notified to the Agency with contact information;
34) ,,corrective action" means activity undertaken by the manufacturer or its authorized representative in the event of a potential or actual non-conformity of a medical device or other undesirable situation. There may be more non-conformities. A corrective measure is

taken to prevent repetition, while preventive measures are taken to prevent such an event (Corrective and Preventive Action - CAPA);

35) ,,user" means a healthcare institution, healthcare professional, healthcare associate or a patient, i.e. person using the medical device;

36) ,,clinical investigation of a medical device" (hereinafter: ,,clinical investigation") means any systematic research, investigation or study involving one or more human subjects, undertaken to assess the safety or performance of a medical device;

37) ,,compatibility of a medical device" means the ability of a medical device, including software, when used together with one or more other devices in accordance with its intended purpose, to:
- perform without losing or compromising the ability to perform as intended, and/or
- integrate, and/or operate without the need for modification or adaptation of any part of the combined devices, and/or
- be used together without conflict/interference or adverse reaction;

38) ,,medical device" (general) means any instrument, apparatus, appliance, software, implant, reagent, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used for diagnostic or therapeutic purposes and which is program support necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:
- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or disability;
- investigation, replacement or modification of the anatomy or of physiological or pathological process or state;
- providing information by means of *in vitro* investigation of specimens from the human body, including organs, blood and tissues donations;
- control or facilitation of conception;
- cleaning, disinfection or sterilization of medical devices.

Medical device referred to in paragraph 1 of this item does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means;

39) ,,custom-made device" means any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics of the medical device and is intended for the sole use of a particular patient. Custom-made device may be prescribed or ordered by a person authorized in accordance with the law i.e. possessing corresponding professional qualifications to do so. Mass-produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user shall not be considered to be custom-made devices;

40) ,,investigational medical device" means any medical device intended for use by a duly qualified medical practitioner when conducting investigations in in an adequate human clinical environment.

For the purpose of conducting clinical investigation, any other person who, in accordance with the law or by virtue of his professional qualifications, is authorized to carry out such investigation shall be accepted as equivalent to a duly qualified medical practitioner;

41) ,,single-use medical device" means a medical device intended to be used only once for a single patient during a single procedure. A single-use medical device may be used repeatedly during a single procedure on the same patient or on the same patient over an extended period of time during a single procedure.
Critical single-use medical device is a single-use medical device intended for use in surgical invasive procedures;
42) ,,multicentric clinical investigation" means a clinical investigation performed according to a unique protocol at multiple clinical investigation sites and conducted by several investigators, regardless of whether the clinical investigation sites are in the same country or in different countries;
43) ,,intended purpose" means the use for which a device is intended according to the data supplied by the manufacturer on the labeling, in the instructions for use and/or in promotional materials;
44) ,,improper use" means the act or omission by a person who handles a medical device or a user, the consequence of which is the performance of a medical device that is outside of any risk control method by the manufacturer;
45) ,,clinical investigation sponsor" (hereinafter: ,,sponsor") means any legal or natural person that takes responsibility for the initiation, i.e. obtaining of authorization for the conduct of a clinical investigation, conducting and financing of the clinical investigation;
46) ,,label" means the written, printed or graphic information appearing on the medical device itself, on the packaging of each component of a medical device or on the packaging of a system or kit and which contains information on the manufacturer's authorized representative and the number of the medical device registration. The label with the information on the number of the medical device registration in Montenegro may also be on the instructions for use;
47) ,,adverse event in a clinical investigation" means any untoward medical occurrence, unintended disease or injury or any untoward clinical signs (including an abnormal laboratory finding) in subjects, users or other persons, whether or not related to the investigational device. This definition includes events related to an investigational medical device or with the medical device it is compared with, as well as events related to the procedures involved. For users or other persons, this definition is limited to events relating to an investigational medical device;
48) ,,adverse effect in a clinical investigation" means an undesired event in connection with the use of an investigational medical device. This definition includes adverse effects arising from insufficient or inadequate instructions for use, development, implantation, installation or operations or any malfunctioning of the investigational medical device. This definition includes any event resulting from an error in use or from the deliberate misuse of an investigational medical device;
49) ,,conformity assessment" means any activity which determines whether a medical device or the manufacturing process of a medical device is in conformity with the prescribed technical requirements, i.e. with the essential requirements under this Law, in order to ascertain that the medical devices is safe and functions in accordance with the intended purpose;
50) ,,serious public health threat" means any event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, which includes:

- events that are significant and unexpected in nature so that they become alarming as a potential public health threat (e.g. human immunodeficiency virus (HIV) or Creutzfeldt-Jakob disease (CJD)). This public health threat may be identified by the Ministry, Agency or the manufacturer, or the authorized representative of the manufacturer,
- the possibility of multiple deaths at short intervals;

51) ,,manufacturer of a medical device" (hereinafter: ,,manufacturer") means the natural or legal person with responsibility for the design, manufacture, packaging and labeling before placing it on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party;
52) ,,authorised representative of the medical device manufacturer" means any natural or legal person established within Montenegro who is explicitly designated in writing by an established or a non-established manufacturer in Montenegro to act and may be addressed instead of the manufacturer and to conduct procedures stipulated under this Law and which is responsible for the safety and performance of a particular medical device in the same manner as the manufacturer of that medical device;
53) ,,benefit-risk ratio" means the assessment of positive effects of a medical device in relation to its risks;
54) ,,quality assurance" means a traceable process by which the quality is introduced into all stages of manufacturing, including the system of documented monitoring of all starting materials and components and individual manufacturing process, i.e. technical assessment, which includes all controls in relation to the quality of the medical device;
55) ,,authorized body" means a conformity assessment body, i.e. a testing laboratory, controlling body and certification body, authorized by the state administration authority in charge of health affairs (hereinafter: Ministry) to perform technical assessment tasks for the needs of the state administration body that conducts the conformity assessment;
56) ,,serious adverse event in a clinical investigation" means any adverse event that led or may lead to death or serious deterioration in the health of the subject, that resulted in a life-threatening illness or injury or permanent impairment of a body structure or a body function, hospitalization or prolongation of patient hospitalization, medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function, chronic disease and leading to fetal distress, fetal death or a congenital physical or mental impairment or birth defect. Planned hospital treatment for a pre-existing condition or a procedure that requires a clinical investigation plan, without serious deterioration in health, shall not be considered a serious adverse event;
57) ,,medical device performance" means the ability of a medical device to achieve its intended purpose as stated by the manufacturer;
58) ,,entrepreneur" (hereinafter: natural person) is a person engaged in an economic activity for the purpose of gaining profit, and this activity is not performed for the account of another. An entrepreneur shall be responsible for all obligations related to the economic activity it performs with its entire property in accordance with the regulations governing companies;
59) ,,accessory for a medical device" means a product which, whilst not being an in vitro medical device, is specifically intended by its manufacturer to be used together with a medical device to enable the medical device to enable that device to be used in accordance with its intended purpose stated by the manufacturer.

An invasive sampling device or those which is directly applied to the human body for the purpose of obtaining a specimen shall not be considered as an *in vitro* diagnostic medical device but a general medical device;

60) ,,post-market surveillance" means all activities carried out by manufacturers, i.e. manufacturers' authorized representatives, to establish and maintain a systematic procedure to proactively collect and review experience gained from medical devices they place on the market or put into service, for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions;
61) ,,notified body" means the conformity assessment body notified to the European Commission by the competent authority of a particular EEA Member State, or of a country with which the European Commission has concluded a contract on the mutual recognition of conformity assessment procedures, for carrying out the conformity assessment procedures of a medical device with the requirements of the European Union legislation, which has its own identification number. The list of the approved notified bodies for medical devices can be found in the ,,NANDO" database of the European Commission;
62) ,,periodic safety update report" means the method of reporting agreed between the Agency and the manufacturer or the manufacturer's authorized representative on the reporting of similar incidents of the same medical device or type of medical device in an unified manner when the cause is known or a Field Safety Corrective Action is implemented;
63) ,,post-market clinical follow-up" means the clinical investigation carried out after the conformity assessment is completed, i.e. after affixing the conformity mark. Post-market clinical follow-up may be interventional and non-interventional;
64) ,,clinical investigation plan" (CIP) (hereinafter: ,,protocol") means a document that describes the rationale, objectives, design, proposed analyses, methodology, monitoring, conduct and records of a clinical investigation;
65) ,,manufacturing process" means any process applied in the manufacturing of medical devices, from the procurement and acceptance of the starting materials, manufacture, packing into the inner packaging to the labeling and the process of packing into the outer packaging;
66) ,,fully refurbishing" means the complete renewal of a medical device already placed on the market or put into service or the renewal of a medical device that was already used to in order to be in compliance with the essential requirements, with the assignment of a new lifetime to the refurbished medical device;
67) ,,registration of a medical device" means the procedure of entry of a medical device which has undergone conformity assessment into the register of medical devices maintained by the Agency;
68) ,,registration of a medical device manufacturer, wholesaler and specialized retail store" means the procedure of entry into the registers maintained by the Agency;
69) ,,spare part of a medical device" means a product that is an integral part of a medical device and is supplied and delivered exclusively for the needs of replacement of existing components of a medical device that is in compliance with the essential requirements. Spare part of a medical device shall not be considered a medical device;
70) ,,batch" means a defined amount of starting materials (starting substances or packaging materials) or products made during a single process of production or manufacturing, or in a series of manufacturing processes, which should therefore be homogeneous. A batch implies the total amount of a medical device that has been produced i.e. manufactured from the same

initial amount of starting materials during a single process of production or manufacturing and a single sterilization process, and in the case of continuous production or manufacturing, the total amount of a medical device produced or manufactured in a particular period;

71) ,,medical device conformity certificate" (hereinafter: ,,conformity certificate") means the EC certificate issued by the notified body, i.e. certificate issued by the designated body confirming that a medical device or a group of medical devices of a particular manufacturer is in conformity with the essential requirements;
72) ,,specialized retail store of medical devices" means an outlet carrying out retail trade of medical devices;
73) ,,outer packaging of a medical device" means the packaging which contains the inner packaging of a medical device;
74) ,,expert public' means healthcare professionals who prescribe medical devices, professionals in the field of manufacturing and wholesale and retail sale of medical devices, as well as in the organization of mandatory health insurance;
75) ,,field safety corrective action" (FSCA) means action taken by a manufacturer or authorized representative of the manufacturer to prevent or reduce the risk of death or a serious deterioration in the state of health in relation to the use of a medical device placed on the market. Such actions, regardless of whether they are related to a direct or indirect damage, shall be notified and recorded via field safety notice;
76) ,,field safety notice" (FSN) means a communication sent customers by a manufacturer or an authorized representative of a manufacturer in relation to a field safety corrective action;
77) ,,self-testing device" means any *in vitro* diagnostic medical device intended to be used by lay persons in a home environment;
78) ,,device for performance evaluation" means any *in vitro* diagnostic medical device intended by the manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analyses or in other appropriate environments outside his own premises;
79) ,,placing on the market" means the first making available in return for payment or free of charge of a medical device other than a device intended for clinical investigation, with a view of distribution and/or use on the market of Montenegro, regardless of whether it is new or fully refurbished;
80) ,,putting into service" means the stage at which a medical device has been made available to the final user as being ready for use on the market of Montenegro for the first time for its intended purpose;
81) ,,damage" means physical injury or damage to the health of people, animals or damage to property or the environment;
82) ,,conformity assessment body" means a legal person that performs conformity assessment i.e. technical evaluation activities, including calibration, investigation, certification and control. Conformity assessment body is the notified body, designated body or authorized body (laboratories, certification bodies, control organizations etc.);
83) ,,transit" means the transportation of medical devices through the territory of Montenegro, without changing the ownership of the consignment and without changing the final destination and the user;
84) ,,market surveillance" means activities carried out and measures taken by competent authorities to check and ensure that medical devices comply with the essential requirements and do not endanger health, safety or any other aspect of public interest protection;

85) ,,technical evaluation of medical device" (hereinafter: ,,technical evaluation") means the investigation or control of the medical device carried out by an authorized conformity assessment body for the needs of the Ministry in accordance with this Law and its implementing regulations;
86) ,,importer" means any legal or natural person established in the European Union (hereinafter: ,,EU") that imports medical devices from third countries i.e. non-EU Member States;
87) ,,inner packaging of a medical device" means the packaging that is in immediate contact with the medical device;
88) ,,off-label use" means medical device application for indications, dosage, method of administration or age group of the patient that are not specified in the labeling data and the data in the instructions for use;
89) ,,medical device vigilance" (hereinafter: ,,vigilance") is a system and set of activities that provide collection, evaluation, understanding and response to knowledge of the risks arising from the use or application of a medical device, in particular with regard to reporting incidents in order to improve and protect the health and safety of patients, users and other persons, and if necessary to provide information that reduce the likelihood of the incident being repeated or alleviating the consequences of that incident;
90) ,,common specifications" (CS) means a set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a medical device, process or system, adopted by the European Commission for specific groups of products not intended for medical purposes.
Common technical specifications are requirements for the assessment and re-evaluation of *in vitro* effects of diagnostic medical devices, requirements for the batch release of an *in vitro* diagnostic medical device to the market, reference methods and reference materials issued by the European Commission.
91) ,,medical device marking of conformity" means a marking affixed on the medical device by the manufacturer confirming that the medical device is in conformity with the essential requirements. Marking of conformity may be a foreign marking of conformity (CE marking) or other marking of conformity of a medical device in accordance with the law on technical regulations.

II COMPETENCIES

Article 10

Ministry shall:
1) pass regulations for the implementation of this Law;
2) prescribe the content and manner of keeping registers of: legal entities for conformity assessment, manufacturers, legal persons and entrepreneurs dealing with wholesale, import and export of medical devices, specialized retail stores, as well as medical devices;
3) designate i.e. authorize legal persons for conformity assessment of medical devices with the essential requirements;
4) carry out other tasks in accordance with this Law.

Article 11

Administration authority in charge of inspection affairs shall:

1) carry out inspection surveillance over manufacturers, legal and natural persons who perform marketing in accordance with the law;
2) carry out inspection surveillance over legal persons for conformity assessment of medical devices;
3) prohibit marketing, or order suspension of marketing or withdrawal from market of medical devices not meeting the prescribed essential and special requirements.

Article 12

The Agency shall:

1) enter, delete and keep a register of manufacturers and legal persons that perform wholesale, import and export of medical devices, as well as a register of specialized retail stores;
2) enter, delete and keep a register of medical devices that may be marketed in Montenegro;
3) grant authorization for import of medical devices referred to in Article 68 of this Law;
4) grant authorization for the commencement of clinical investigations and control the implementation of clinical investigations;
5) implement a system of vigilance;
6) decide on the classification of medical devices when it comes to the combination of medicines and medical devices, medical devices and objects of general use or classification of medical devices and gives expert opinions from their jurisdiction;
7) in the procedure for determining the conformity of medical devices with the requirements prescribed by this Law, give opinion to a designated and authorized body;
8) cooperate with international entities and national regulatory bodies in the field of medical devices;
9) perform other tasks, in accordance with the law.

When performing the tasks referred to in paragraph 1 items 1, 2, 3, 4 and 6 of this Article, the Agency shall issue a decision.

The tasks referred to in paragraph 1 items 1 to 7 of this Article shall be carried out by the Agency as tasks under delegated jurisdiction.

Article 13

Expenses incurred in the performance of expert tasks in the procedure of issuing the decision referred to in Article 12 paragraph 1 items 1 to 6 of this Law shall be borne by the applicant submitting the application or the request, unless otherwise prescribed by this Law.

The Agency shall charge an annual fee for the decision on entry into the register of medical devices, entry into the register of manufacturers of medical devices, legal entities that carry out wholesale and retail sale, and the entry into the register of importers of medical devices.

The method of payment of the fees, as well as the amount of the fees referred to in paragraphs 1 and 2 of this Article, which correspond to the actual costs of the executed tasks, shall be determined by the Agency.

The document referred to in paragraph 3 of this Article shall require approval of the Government of Montenegro.

Article 14

For the performance of certain expert and advisory tasks in the decisions making procedure on classification of medical devices, as well as other expert tasks referred to in Article 12 of this Law, requiring special expert knowledge of medicine, dentistry, pharmacy, veterinary or other related

fields, or technical areas related to the manufacturing of medical devices, the Agency shall form commissions, i.e. establish a list of experts from the ranks of prominent experts from the mentioned fields.

The expenses for the work of the commission and experts referred to in paragraph 1 of this Article shall be provided from the Agency's resources.

Article 15

The Director and the employees of the Agency cannot perform, on their own behalf and for their own account, and on behalf and for the account of another legal or natural person, the tasks of designing, manufacturing, and marketing of medical devices, nor can they have other personal interest (ownership, shares, membership in a management body or contractual relationship) with a person who deals with these activities, which they will confirm by signing a statement.

The persons referred to in paragraph 1 of this Article, as well as the members of the commissions and experts from the list of experts, cannot represent legal and natural persons connected with the manufacturing and marketing of medical devices, which they will confirm by signing a statement.

The Director and the employees of the Agency, as well as experts and members of the commission referred to in the Article 14 of this Law shall sign a confidentiality statement for the data falling within the competence of the Agency.

III CLASSIFICATION OF MEDICAL DEVICES

Article 16

Types of medical devices shall include:

1) general medical devices;
2) *in vitro* diagnostic medical devices;
3) active implantable medical devices.

Article 17

According to the level of risk to the user, general medical devices are divided into:

1) class I – medical devices with low risk level;
2) class IIa – medical devices with low to medium risk level;
3) class IIb – medical devices with medium to high risk level;
4) class III – medical devices with high risk level.

Detailed conditions and method of classification of individual medical devices referred to in paragraph 1 of this Article and Article 16 of this Law shall be regulated by the Ministry.

Article 18

Classification of medical devices shall be carried out by the notified, or designated body in accordance with the essential requirements, except for class I medical devices and *in vitro – Other* diagnostic medical devices, the classification of which shall be carried out by the manufacturer.

In the event of a dispute between the manufacturer and the designated body regarding the determination of the class of a medical device, the decision shall be made by the Ministry based on the opinion of the authorized body.

If the classification referred to in paragraph 2 of this Article is under dispute, it shall be decided by the Agency.

In case of a combination of a medicine and a medical device or a medical device and a product of general use, classification shall be carried out according to the primary intended purpose stated by the manufacturer and the effect mechanism of the product itself.

Article 19

Any legal or natural person who puts medical devices with a marking of conformity together within their intended purpose and within the limits of use stated by their manufacturer, in order to place them on the market as a system or a procedure pack, shall draw up a declaration by which he states that:

1) he has verified the mutual compatibility of medical devices that are integral parts of the system or procedure pack and performed the assembly procedure in accordance with the manufacturer's instructions;

2) he has packaged the system or procedure pack and provided the user with instructions for use, including appropriate instructions for use from the manufacturer;

3) the relevant methods of internal control of medical device manufacturing apply to the activities referred to in items 1 and 2 of this paragraph.

If the conditions referred to in paragraph 1 of this Article are not met, as in cases where the system or procedure pack incorporate medical devices that do not bear a marking of conformity or when a combination of selected medical devices is not compatible in view of their original intended use, the system or procedure pack shall be treated as a medical device in its own right and as such be subjected to the conformity assessment procedure.

Article 20

Any legal or natural person who sterilises, for the purpose of placing on the market systems or procedure packs referred to in Article 19 paragraph 1 of this Law or other medical devices with a marking of conformity designed by their manufacturers to be sterilized before use shall, at his choice, carry out the sterilization procedure in accordance with the corresponding quality system for the sterilization process prescribed by law and shall draw up a declaration stating that the sterilization has been carried out in accordance with the manufacturer's instructions.

The application of the procedures referred to in paragraph 1 of this Article shall be limited to achieving sterility until the opening of the sterile packaging or its damage.

The systems and kits referred to in paragraph 1 of this Article shall not bear an additional marking of conformity.

Systems and kits shall be accompanied by instructions for use that, if necessary, include information from the manufacturer on the medical devices that constitute the system or kit.

The manufacturer shall keep the statements referred to in Article 19 paragraph 1 of this Law and paragraph 1 of this Article for five years and deliver them at the request of the Ministry or the designated body.

IV. REQUIREMENTS TO BE MET BY MEDICAL DEVICES

Article 21

Medical devices may be placed on the market and put into service in Montenegro only if they do not endanger the health and safety of patients, users and other persons, if they are properly manufactured, procured and installed, maintained and used in accordance with their intended purpose.

Medical devices must meet the essential requirements taking into account the intended purpose of the medical device concerned.

A medical devices which are a source of ionizing radiation must also meet the requirements laid down by the regulations governing the protection against ionizing radiation.

When there is a significant risk, medical devices that are simultaneously machinery must meet the prescribed essential health and safety requirements to the extent that these requirements are more specific than the essential requirements prescribed by this Law.

If the medical device is also intended to be used as personal protective equipment, the medical device must also meet the relevant essential requirements in accordance with the regulations governing safety at work.

Detailed contents of the essential requirements for medical devices, as well as the special requirements for medical devices referred to in Article 4 of this Law, shall be prescribed by the Ministry.

Article 22

Medical device shall meet the relevant essential requirements if it meets the requirements of the Montenegrin standards transposing the corresponding harmonized European or international standards the list of which is published in the ,,Official Gazette of Montenegro" in accordance with the law regulating the technical requirements for products and conformity assessment.

The standards shall also include national pharmacopoeia monographs, as well as applicable European pharmacopoeia, notably on surgical sutures and on interaction between medicines and materials used in medical devices containing such medicines.

Article 23

The regulations governing the field of technical requirements for products and conformity assessment shall apply to any matters related to the conduct of conformity assessment, designation and authorization of the medical device conformity assessment bodies, the conditions, requirements and obligations for the authorized or designated bodies, the content and validity of the conformity document and the marking of conformity, notification on technical regulations, and notification of the designated or authorized conformity assessment body.

Article 24

Conformity assessment procedure of a medical device shall establish and assess whether the medical device or the manufacture of a medical device meets the requirements prescribed by this Law.

Assessment of conformity of a medical device with the essential requirements before placing it on the market shall be carried out by the manufacturer or the conformity assessment body, at the request of the manufacturer or the authorized representative of the manufacturer.

Technical assessment shall be carried out by the conformity assessment body by controlling the final product according to the technical specification, in accordance with this Law.

Article 25

The process of conformity assessment with the essential requirements shall be carried out depending on the medical device risk class.

Conformity assessment of class I medical devices (other than class I sterile products and products having a defined measuring scale, which are treated as higher class medical devices) and for *in vitro -Other* diagnostic devices shall be carried out by the manufacturer itself.

Conformity assessment of certain *in vitro* diagnostic medical devices shall be carried out in accordance with the common technical specifications.

If, for justified reasons, an *in vitro* diagnostic medical device fails to meet the common technical specifications, the manufacturer shall apply the solutions that ensure safety and efficacy and whose level of requirements is at the level of the common technical specifications.

If the conformity assessment procedure requires the involvement of a conformity assessment body, the manufacturer shall select a conformity assessment body with the relevant jurisdiction, i.e. the notified body or the designated body.

Assessment of conformity with the national pharmacopoeia monograph, as well as the valid European or international pharmacopoeias referred to in Article 22 paragraph 2 of this Law shall be carried out by the body authorized for conformity assessment.

Conformity assessment of products referred to in Article 3 of this Law shall be carried out in accordance with the common specifications.

Detailed conditions of conformity assessment and the type of conformity document shall be prescribed by the Ministry.

Article 26

Conformity of a medical device with the prescribed requirements shall be confirmed by way of a conformity document.

Prior to placing a medical device on the market, the manufacturer shall give a declaration of conformity for that product and mark it with a CE marking or another appropriate marking of conformity.

Conformity assessment bodies shall issue conformity documents and affix CE marking or other appropriate marking of conformity, which is valid maximum five year.

Recognition of a conformity document and the CE marking referred to in paragraphs 2 and 3 of this Article issued by the conformity assessment body, which is not established in Montenegro, shall be done by the Agency in the procedure for registration of a medical device.

Notwithstanding paragraph 4 of this Article, the Agency may also issue a decision on the recognition of a foreign document or CE marking at the request of the manufacturer or an authorized representative of the manufacturer of a medical device.

Detailed conditions, manner and procedure for the recognition of foreign documents and CE markings shall be prescribed by the Ministry.

Article 27

Manufacturer or his authorised representative must, for a period ending at least five years, and in case of implantable medical devices at least 15 years, after the last medical device has been manufactured, keep at the disposal of the administrative authority in charge of inspection affairs: the declaration of conformity, document of conformity, technical documentation prescribed by this Law, as well as the decisions, reports and certificates issued by the conformity assessment body.

Article 28

Medical device when they are placed on the market and/or put into service in Montenegro must bear CE marking or other appropriate marking of conformity in accordance with the conformity document.

The marking of conformity must appear in a visible, legible and indelible form on the medical device itself or on its sterile pack, where practicable and appropriate, and on the instructions for use.

Where applicable, the conformity marking must also appear on the sales packaging.

It is prohibited to affix marks or inscriptions that are likely to mislead third parties with regard to the meaning or graphics of the marking of conformity.

Any other mark may be affixed on a medical device, to the packaging or to the instruction leaflet accompanying the device, if the visibility and legibility of the marking of conformity is not thereby reduced.

Article 29

Custom-made medical devices for specific patient or medical device for clinical investigation do not need to bear CE marking or other appropriate marking of conformity. These devices shall be accompanied by the manufacturer's declaration of the special intended purpose of the medical device in accordance with this Law.

Medical devices intended for exhibitions, demonstrations, trade fairs, etc. do not have to be marked with a CE marking or other appropriate marking of conformity, provided that a visible sign clearly indicates that such devices cannot be marketed or put into service until they have been made to comply.

Article 30

When other regulations prescribing the obligation to affix the marking of conformity apply to a medical device, the marking is proof that the medical device meets the prescribed conditions.

If one or more regulations allow the manufacturer to choose which solution to apply during a transitional period, the marking of conformity shall indicate that the medical device fulfil the provisions of the regulations applied by the manufacturer.

In the case referred to in paragraph 2 of this Article, the manufacturer must document the particulars from those regulations in the notices or instructions for use required by those regulations and accompanying such medical device.

Article 31

A conformity assessment body established in Montenegro that carries out conformity assessment of medical devices or performs technical assessment tasks shall submit an application with the Ministry before the commencement of the activity to obtain a decision on authorization or designation in accordance with this Law and the regulations governing technical requirements for products and conformity assessment.

Article 32

The Ministry shall issue a decision on the authorization or designation referred to in Article 31 of this Law within 60 days from the date of receipt of the complete application.

During the course of the procedure, the Ministry may request additional information necessary to assess the fulfillment of the conditions for designation or authorization.

If the request referred to in the Article 31 of this Law is not complete, the Ministry shall inform the applicant in writing asking it to eliminate deficiencies within 30 days and deliver the requested data and documents.

The deadline referred to in paragraph 1 of this Article shall start to run on the date of submission of the requested data and documents.

In the course of the procedure, the Ministry may verify the said data, as well as other data of importance for public health.

Detailed requirements for obtaining the authorization or designation referred to in paragraph 1 of this Article shall be prescribed by the Ministry.

Article 33

If the Ministry determines that the authorized or designated body has ceased to fulfill the conditions or does not fulfill its obligations in accordance with this Law, it shall issue a decision repealing the decision on authorization or designation.

Prior to the issuance of the decision referred to in paragraph 1 of this Article, the Ministry may, taking into account the type of deficiency in respect of the fulfillment of the essential requirements or the fulfillment of obligations, warn the authorized or designated body, in written or electronic form, to eliminate the deficiencies within 60 days.

If the Ministry passes the decision referred to in paragraph 1 of this Article or if the authorized or designated body cease to operate, the Ministry may order the body to carry out the transfer of documentation relating to the conformity assessment to another authorized or designated body at the choice of the manufacturer within the specified time limit, or to make the documentation available to the competent authorities.

The Ministry shall keep records of authorized or designated conformity assessment bodies in the field of medical devices.

Article 34

The designated body and the manufacturer shall determine by mutual agreement the deadlines for carrying out the conformity assessment and conformity verification procedures prescribed by this Law and the technical regulation, related to type testing, verification, quality assurance of manufacturing and quality assurance of the medical device.

In the conformity assessment procedure, the designated body or the manufacturer shall take into account the results of all assessment and verification procedures that have been carried out, as required, in accordance with this Law.

The designated body shall inform the Ministry and the Agency of all issued, amended, suspended, withdrawn, restricted or certificates whose issuance has been refused.

The designated body shall also inform other conformity assessment bodies designated in accordance with this Law of certificates suspended, withdrawn or whose issuance was refused, and the manufacturer, upon request.

The designated body shall, at the request of the Ministry and the Agency also provide other additional relevant information and documentation.

When the designated body establishes that the essential requirements are not fulfilled or that the manufacturer no longer fulfills them or that the certificate should not have been issued, the designated body shall suspend, withdraw or restrict the issued certificate, in relation to the type and scope of non-conformity, unless the manufacturer ensures compliance with the essential requirements by applying the appropriate corrective measures.

The designated body shall, upon request of the Ministry, provide relevant information and documentation, including financial documentation.

The designated body may, where justified, request the manufacturer to supply all the information and data necessary to establish and maintain a certified conformity with respect to the selected conformity assessment procedure.

If the conformity assessment was carried out by the notified body, the obligations referred to in paragraphs 3 and 4 of this Article shall apply to the manufacturer or authorized representative of the manufacturer.

Article 35

Provisions governing the essential requirements for the safety and performance of a medical device, shall be applied to a medical device that is produced in a healthcare institution for use only in healthcare institutions, provided that:

1) the medical device is not in any way provided to another legal or natural person with or without charge;

2) the production of the medical device is carried out in accordance with the appropriate quality management system;

3) the healthcare institution establishes in its records that the specific needs of a patient or a group of patients cannot be fulfilled or cannot be fulfilled at the appropriate level of performance by an equivalent medical device available on the market;

4) the healthcare institution, upon the request of the Agency and the Ministry, delivers information on the use of these medical devices, with an explanation of their manufacturing, modification and use;

5) the healthcare institution issues and makes publicly available a statement, which includes: the name and address of the healthcare institution that produces the medical device, details necessary for the identification of the medical device, a statement guaranteeing that the medical device meets the general requirements for safety and performance in accordance with this Law i.e., if necessary, information stating which requirements have not been met, with an explanation;

6) the healthcare institution draws up documentation on the space, equipment, personnel and manufacturing process , design and performance of the medical device, including the intended purpose, in sufficient detail to allow the Agency to determine that the general safety and performance requirements are met, in accordance with this Law;

7) the healthcare institution takes all necessary measures to ensure that the medical device is made in accordance with the documentation referred to in item 6 of this Article;

8) the healthcare institution, on the basis of the experience acquired from the clinical use of the medical device, undertakes all necessary corrective measures.

Article 36

A medical device produced in a healthcare institution may be put into use in that healthcare institution and must not be placed on the market in Montenegro.

The authority in charge of inspection affairs may prohibit or restrict the production and/or use of the medical device referred to in paragraph 1 of this Article if the healthcare institution fails to meet or ceases to meet the conditions prescribed by this Law.

The Agency shall keep records of healthcare institutions that produce medical devices referred to in Article 35 of this Law.

Detailed conditions for the general requirements for the safety and performance of the medical device referred to in Article 35 of this Law shall be prescribed by the Ministry.

V REGISTRATION OF A MEDICAL DEVICE

Article 37

The Agency shall register a medical device for which the conformity assessment has been carried out and which is placed on the market or put into service, by entering it in the register of medical devices (hereinafter: the register) unless otherwise provided by this Law.

Registration of a medical device in accordance with this Law is not a condition for placing a medical device on the market, or putting it in service.

Article 38

The person submitting an application for registration of a medical device may be:

1) the manufacturer of a medical device established in Montenegro, or its authorized representative;

2) for the manufacturer of a medical device not established in Montenegro, its authorized representative, which is established in Montenegro.

The applicant referred to in paragraph 1 of this Article must have an employed person responsible for documentation and an employed person who is responsible for vigilance, and must be permanently available.

The person responsible for documentation for the activities in the procedure of registration, amendments, extension or deletion from the register may be a person who has completed a medical or technical faculty or a faculty of law.

The person responsible for vigilance and monitoring of the medical device on the market may be a person who has completed a medical or technical faculty depending on the type of medical device, as well as additional education in the field of vigilance.

The applicant referred to in paragraph 1 of this Article shall be responsible for the credibility of the documentation in the procedure for registration of a medical device.

Article 39

Application for registration of a medical device shall be submitted to the Agency.

The application referred to in paragraph 1 of this Article shall contain:

1) a list of medical devices for which registration is requested (if they are of the same class, category and from the same manufacturer);

2) name and residence or domicile of the applicant and name and seat of the manufacturer;

3) name of the responsible person for the registration process;

4) relevant document or declaration of conformity;

5) the authorization of the manufacturer given to authorized representative to carry out the registration of the medical device on its behalf on the territory of Montenegro; and

6) other information relevant for obtaining a decision on registration of the medical device, in accordance with this Law.

An application for registration of a medical device may be submitted by a natural or legal person with seat or residence or domicile in Montenegro for one medical device.

Article 40

Within 90 days from the date of submission of the complete documentation, the Agency shall enter in the register: the medical device, the manufacturer, the legal entity that deals with wholesale and retail sale of the medical device and the importer.

The Agency may during the registration process request from the applicant to submit additional information necessary for assessing the fulfillment of the registration requirements.

If the application for registration is not complete, the Agency shall inform the applicant in writing asking it to rectify the deficiencies and submit the required data and documents within 30 days.

The deadline referred to in paragraph 1 of this Article shall not run until the required data and documents are supplied.

In the framework of the application procedure, the Agency may verify the said data, as well as other information of importance for public health.

Article 41

The Agency shall issue a decision on the registration of a medical device whose validity period cannot be longer than 60 days after the expiry of the validity of the conformity document.

For class I medical devices (other than class I sterile (Is) and class I measurement (Im)), as well as class *in vitro diagnostic - Other* medical devices, which are marketed on the basis of a declaration of conformity issued by the manufacturer, the decision on the registration of the medical device shall be issued for a period of five years.

Medical devices may be on the market for a maximum of 90 days from the date of expiration of the decision on the registration of a medical device, unless an application for the extension of the registration of a medical device has been filed.

Within the deadline referred to in paragraph 3 of this Article, import of the medical device whose decision on entry in the register of medical devices has expired, shall be prohibited.

Article 42

The entities referred to in Article 40 paragraph 1 of this Law shall submit to the Agency an application for any amendment of the data from the register, prior to the introduction of the change.

If the application for amendments of the registration is not complete, the Agency shall inform the applicant in writing to rectify the deficiencies within 30 days and deliver the requested information and documents.

The Agency shall issue a decision on amendments of the registration, within 60 days from the date of submission of the complete application.

Amendments to the registration that are administrative in nature and do not require a change of the registration decision shall be notified to the Agency.

Within the application procedure, the Agency may verify the said data, as well as other information of relevance for public health, and give a negative opinion on the notified amendments.

Amendments to the registration referred to in paragraph 4 of this Article shall be entered in the register without issuing the decision referred to in paragraph 3 of this Article, with a notification to the applicant.

Article 43

The manufacturer or a new authorized representative shall notify, without delay, any change of the authorized representative of the manufacturer.

The method of changing the authorized representative shall be defined by way of a contract, which is, as a rule, concluded between the manufacturer and the future authorized representative, and which shall include:

1) the date of termination of the authorization of the existing authorized representative and the starting date of the authorization of the future authorized representative;

2) the date by which the existing authorized representative of the manufacturer can be indicated in the data provided by the manufacturer in accordance with this Law, including the promotional material;

3) transfer of documents, including aspects of confidentiality and property rights;

4) the obligation of the existing authorized representative to deliver to the manufacturer or to the future authorized representative, after the expiry of the authorization, every notification or complaint, quality defect and incident, filed by healthcare professionals, patients, or users of the medical device for which it was designated as an authorized representative.

Article 44

The manufacturer shall submit to the Agency the application for extension of the registration of a medical device before the expiration of the deadline for which the decision on the registration of the medical device was issued.

The Agency shall issue a decision on the extension of the registration of a medical device within 60 days from the date when the application was filed.

Article 45

The manufacturer or his authorized representative shall place a medical device on the market within 12 months from the date of delivery of the decision referred to in the Article 42 paragraph 3 of this Law in accordance with that decision, or notification referred to in the Article 42 paragraph 4 of this Law.

Article 46

The Agency shall issue a decision on the deletion of a medical device from the register of medical devices, without delay:

1) if the medical device is not safe under the prescribed conditions of use;

2) if the data on the medical device in the register of medical devices are not accurate or not complete;

3) based on written notification of the manufacturer or his authorized representative ;

4) upon a proposal from the administrative authority in charge of inspection affairs in the case referred to in Article 133 of this Law.

If no application for extension of registration of a medical device is filed in accordance with Article 44 paragraph 1 of this Law, the Agency shall remove the medical device from the register of medical devices without issuing a special decision.

Article 47

The Agency shall publish the entry, amendments of the data on registration of a medical device, extension of registration and removal from the register of a medical device on its website within 15 days.

Detailed contents of the application, documentation, as well as the manner of registration, extension of the period of the decision on registration, amendments and deletion of the medical device from the register of medical devices, shall be prescribed by the Ministry.

Article 48

Medical device shall not be registered:

1) if the authorisation for conducting a clinical investigation has been issued for it;

2) if it is intended for the continuation of treatment initiated outside the territory of Montenegro for personal use of a particular patient upon the proposal of the competent healthcare professional in the country in which the treatment was initiated;

3) if it was custom-made;

4) if it is intended for scientific research and development;

5) if it is temporarily imported for the purpose of displaying at exhibitions and trade fairs;

6) if it is produced in a health institution, for use in that health institution in accordance with this Law.

VI MANUFACTURING OF MEDICAL DEVICES

Article 49

The manufacturing of medical devices shall include the design, manufacturing, packaging and labeling, quality assurance system, storage, placing on the market and distribution of medical devices.

The activity of the manufacturing of medical devices also include the sale of these products to legal entities that carry out wholesale of medical devices.

Article 50

The provisions of this Law that apply to the manufacturers shall apply to legal and natural persons who assemble a system or a procedure pack, pack, reprocess, fully refurbish and label one or more finished products and determine the intended purpose of the medical device for the purpose of placing on the market under their name.

By way of derogation from paragraph 1 of this Article, registration of the manufacturer shall not be required for legal and natural persons who assemble or adapt medicinal devices of a specific intended purpose that are already on the market and are intended for a particular patient.

Article 51

The manufacturing of medical devices shall be carried out in accordance with the established system of quality assurance of the medical device manufacturing, proven by the manufacturer by way of a certificate issued by the certified body.

If the manufacturer does not have a quality assurance system referred to in paragraph 1 of this Article, it shall provide a quality system in accordance with this Law.

Article 52

The manufacturing of medical devices may be carried out only by registered legal and natural persons, in accordance with this Law.

Article 53

The application for registration of a manufacturer shall be submitted to the Agency and it shall contain:

1) the name and residence or domicile or name and seat of the manufacturer and place of manufacturing;

2) a description of the medical devices to be manufactured;

3) a description of the procedure or part of the procedure of manufacturing of medical devices for which the manufacturer's registration is done;

4) the name of the person responsible for the manufacturing and the person responsible for quality and vigilance;

5) data on the personnel, equipment and space, in accordance with this Law;

6) a list of equipment for manufacturing with certificates or technical data on the equipment;

7) information on waste management and environmental protection;

8) evidence of a system of quality assurance of the medical device manufacture in accordance with Article 51 of this Law; and

9) other information significant for the registration of the manufacturer, in accordance with this Law.

Application for the registration of a medical device manufacturer which does not have residence or domicile or seat in Montenegro shall contain:

1) the contract or authorization of the applicant with the medical device manufacturer;

2) the documentation for the responsible persons of the authorized representative for the registration procedure and vigilance of medical devices

3) other information significant for the registration of the manufacturer, in accordance with this Law.

Detailed conditions, manner of determining the fulfillment of conditions for the manufacturing of medical devices, the content of the decision on the registration of the manufacturer, and the manufacturing of custom-made medical device, shall be prescribed by the Ministry.

Article 54

The manufacturer shall manufacture medical devices in accordance with the essential requirements and the decision issued by the Agency.

The manufacturer must meet the special conditions, as follows:

1) to provide conditions in terms of space and equipment for the manufacturing of medical devices, in accordance with the essential requirements for the medical device whose manufacture he performs;

2) to have at least one employee responsible for manufacture;

3) to have at least one person responsible for quality and vigilance;

4) to ensure that the medical device is designed in accordance with the essential requirements;

5) to classify the medical device in the appropriate risk class, prepare the prescribed technical documentation and implement, or ensure the implementation of the applicable conformity assessment procedure;

6) to issue a declaration of conformity, where applicable, and mark the medical device with a marking of conformity in accordance with this Law;

7) to keep the technical documentation and the declaration of conformity after placing the medical device on the market for at least five years, and for implantable medical devices for at least 15 years;

8) to have in place the procedures ensuring the maintenance of conformity of the medical device manufacture with the essential requirements and technical standards;

9) to label the medical device and attach the instructions for use in accordance with this Law;

10) to take the necessary corrective measures in the event of established non-conformity;

11) for a medical device, except for a custom-made medical device or investigational medical device, to establish and maintain, and to keep proper records of non-compliant medical devices and those withdrawn from the market;

12) to have a plan for the withdrawal of a medical device from the market;

13) to keep records on the type and quantity of sold medical devices in Montenegro; and

14) to provide other conditions for the manufacture in accordance with this Law.

The manufacturer shall provide insurance against harmful effects that may arise when using a medical device, in accordance with the Insurance Law.

Article 55

The manufacturer shall ensure continuous availability of the persons referred to in Article 54 paragraph 2 items 2 and 3 of this Law.

The person referred to in Article 54 paragraph 2 item 2 of this Law shall be responsible for the preparation and implementation of the process of medical device manufacture.

The person referred to in Article 54 paragraph 2 item 3 of this Law shall be responsible for the technical evaluation of each batch of medical device, i.e. responsible for the quality of the medical device during the medical device manufacturing process, including the system of documentary monitoring of all starting materials and components, packaging materials, bulk products, manufacturing processes, as well as the testing of a finished medical device.

The person responsible for vigilance and monitoring of the medical device on the market may be a person who has completed medical or technical faculty depending on the type of medical device, as well as additional education in the field of vigilance.

Article 56

The manufacturer's registration may refer to the entire process or parts of the process of a medical device manufacture.

The decision on the manufacturer's registration shall be issued for an indefinite period.

Article 58

The Agency may pass the decision repealing the decision on medical device manufacture if:

1) the manufacturer fails to carry out manufacture in accordance with the manufacturer's registration, or if it changes the conditions on the basis of which the registration of the medical device was issued, without informing the Agency thereof;

2) the manufacturer ceases to fulfill the requirements prescribed by this Law;

3) it fails to remove within a specified period the deficiencies and irregularities in the operation established by the administrative authority in charge of inspection affairs in accordance with this Law;

4) submits an application for the termination of the manufacturer's registration.

Article 59

The Agency shall remove a manufacturer from the register of manufacturers:

1) upon his reasoned request;

2) *ex officio*, if it determines that the manufacturer was entered in the register of manufacturers contrary to the provisions of this Law;

3) in the case referred to in Article 131 of this Law, on the proposal of the administration authority in charge of inspection affairs.

Article 60

The manufacturer whose manufacturer registration has expired or has been cancelled shall submit an application to the Agency for removal from the register of manufacturers and removal from the register of medical devices within 30 days from the expiration date or the cancellation of the decision.

If the manufacturer fails to submit the application referred to in paragraph 1 of this Article, the Institute shall execute the removal from the register *ex officio*.

VII MARKETING OF MEDICAL DEVICES

Article 61

Marketing of medical devices shall be carried out as wholesale and retail.

Wholesale of medical devices shall include the procurement, storage and distribution, other than the issuance of a medical device to the end user or the patient for his personal needs.

Wholesale of medical devices shall also include import and export of medical devices.

Wholesale of medical devices referred to in paragraph 2 of this Article also include marketing of medical devices from donations or humanitarian aid.

Export for the repair of a medical device of a certain serial number that was in use in Montenegro and the import of that medical device of the same serial number shall not be considered to be marketing as referred to in this Law.

Transit, i.e. import for the purpose of export of a medical device shall not be considered as marketing of a medical device.

Article 62

Wholesale of medical devices may be carried out by:

1) legal persons with a seat in Montenegro which are registered in accordance with the provisions of this Law;

2) manufacturers established in Montenegro for the devices they manufacture.

Marketing of medical devices referred to in paragraph 1 of this Article may be carried out only with medical devices that are registered, i.e. medical devices referred to in Article 66 of this Law that possess a document or declaration of conformity.

Article 63

Legal entities carrying out wholesale of medical devices (hereinafter: „wholesaler") shall carry out wholesale in accordance with the decision on wholesale registration and the guidelines for Good Distribution Practice for medical devices.

Wholesaler shall fulfill special conditions, as follows:

1) to carry out the activity of wholesale of medical devices while ensuring the quality and protection of the health of citizens;

2) in terms of space, equipment and appropriate personnel;

3) to have employed person responsible for vigilance of medical devices;

4) to keep records of the type and quantity of sold medical devices in Montenegro, as well as of imported and exported medical devices by individual packages; and

5) other conditions for wholesale of medical devices in accordance with this Law.

Wholesalers shall ensure continuous availability of the persons referred to in paragraph 2 items 2 and 3 of this Article.

The persons referred to in paragraph 2 item 2 of this Article shall be responsible for the receipt, storage, keeping and delivery of medical devices and they shall possess appropriate medical or technical qualifications and level of education, depending on the type of medical devices being placed on the market.

Person responsible for the vigilance and monitoring of a medical device on the market shall be a person who has completed a medical or technical faculty depending on the type of medical device, as well as additional education in the field of vigilance.

Wholesaler may delegate certain tasks within wholesale of medical devices to another wholesaler.

The guidelines for Good Distribution Practice for medical devices shall be published on the website of the Ministry and the Agency.

Detailed conditions, the manner of determining the fulfillment of conditions and the content of the decision on the wholesaler registration shall be prescribed by the Ministry.

Article 64

Application for wholesaler registration shall be filed to the Agency.

The application referred to in paragraph 1 of this Article shall contain:

1) the name and seat of the legal person;

2) the place of storage of medical devices;

3) a list of medical devices for which the wholesaler registration is requested;

4) the name of the responsible person supervising the receipt, storage, keeping and delivery of medical devices;

5) the plan for urgent withdrawal of medical devices from the market;

6) evidence of availability of vehicles for transport of medical devices; and

7) other information significant for obtaining the wholesaler registration, in accordance with this Law.

The decision on wholesaler registration shall be issued for an indefinite period.

Article 65

The decision on wholesaler registration shall cease to be valid if the wholesaler:

1) ceases to fulfill the conditions for the wholesale of medical devices on the basis of which the wholesaler registration was issued;

2) fails to remove deficiencies and irregularities in the operation determined by the competent inspectorate in accordance with this Law within a specified period;

3) fails to fulfill the obligation of continuous supply of the market with the medical device for which a decision on wholesaler registration was issued, in accordance with this Law;

4) submits an application for removal from the wholesaler register;

5) carries out wholesale of a medical device suspected of being falsified or found to be falsified without informing the Ministry, Agency and the manufacturer.

Article 66

The Agency may authorize the import of medical devices that are not registered in the case of urgent medical need, for the purposes of public health protection, as well as in the following cases:

1) for research purposes;

2) for clinical investigations;

3) in case of natural disasters or

4) other emergency situations.

The medical device referred to in paragraph 1 of this Article shall undergo conformity assessment, or an equivalent assessment of safety and performance in accordance with this Law.

Detailed conditions for the import of medical devices that are not registered shall be prescribed by the Ministry.

Article 67

Application for import of medical devices referred to in Article 66 of this Law shall be filed with the Agency.

The application referred to in paragraph 1 of this Article shall contain:

1) the name and quantity of medical devices being imported;

2) the name and residence or domicile or name and seat of the manufacturer;

3) expert opinion of the responsible person in the healthcare institution for which the medical devices are imported;

4) data on the compliance of a medical device with this Law;

5) other information, at the request of the Agency, in accordance with this Law.

The Agency shall issue a decision approving or rejecting the application for import of a non-registered medical device within 30 days from the date of receipt of the complete application.

Article 68

Import and export of medical devices may be carried out by domestic and foreign legal and natural persons that are registered in the importer's register maintained by the Agency.

Article 69

Importers of medical devices from non-EU countries may place on the market only a medical device for which conformity assessment has been carried out in accordance with this Law.

Before placing the medical device on the market, the importer shall ensure that:

1) the manufacturer has carried out the appropriate conformity assessment procedure for the medical device being imported;

2) the manufacturer has authorized an authorized representative in accordance with this Law;

3) the manufacturer has prepared a declaration of conformity and technical documentation on the medical device being imported;

4) the manufacturer has assigned the medical device with a unique device identification (UDI), or bar code, if applicable;

5) the medical device is marked with a marking of conformity in accordance with this Law;

6) the medical device is labeled in accordance with this Law and accompanied by the instructions for use and the declaration of conformity.

Detailed conditions and the method of importing medical devices from non-EU countries shall be prescribed by the Ministry.

Article 70

Wholesalers shall ensure continuous supply of the market with medical devices in accordance with the decision on wholesaler registration.

Wholesaler shall, upon request of a healthcare institution, specialized retail facility, and other legal person which provides health care in accordance with the law, deliver the medical device for which it has received the wholesaler registration and which is entered in the register of medical devices, as soon as possible.

For the continuous supply of the market with medical devices, the wholesaler shall provide the necessary stocks of medical devices for the wholesale of which it has been issued wholesale registration and which are entered in the register of medical devices, i.e. start procurement or import in a timely manner in order not to interrupt the supply of the market.

Article 71

Wholesalers may procure medical devices directly from the manufacturer, importer or other wholesaler, which are registered in the register maintained by the Agency and possess the license to carry out the activities issued by the competent authority of the country from which the medical devices are imported.

Wholesalers may sell medical devices from their assortment exclusively to medical device manufacturers, other wholesalers, healthcare institutions, specialized retail stores, as well as other legal entities providing health care in accordance with the law.

Notwithstanding paragraph 2 of this Article, the manufacturer and wholesalers may also sell certain medical devices to other legal entities engaged in retail sale in accordance with this Law.

The list of medical devices referred to in paragraph 3 of this Article shall be published on the Agency's website.

Article 72

Wholesalers shall inform the Agency without delay of:

1) all significant changes in terms of personnel, premises or storage location of medical devices and equipment, as well as any delegated duties;

2) any incident that could affect the quality of the medical device or the safe handling;

3) any problem in ensuring the continuous supply of the market with a medical device.

In the cases referred to in paragraph 1 of this Article, on the proposal of the Agency, the administration authority in charge of inspection affairs may issue an order to suspend or prohibit marketing of a medical device or to withdraw a medical device from the market, i.e. the Agency may issue a decision on the removal from the wholesaler register in accordance with this Law.

Article73

Retail sale of medical devices shall be carried out by a pharmacy, veterinary pharmacy and specialized retail store in accordance with this Law.

Marketing of medical devices referred to in paragraph 1 of this Article shall include procurement, storage, transport and dispensing or sale to the user.

Notwithstanding paragraph 1 of this Article, certain types of medical devices may also be sold in other closed retail places in accordance with the regulations governing commerce.

Manufacturer of a custom-made medical device may carry out dispensing or sale of that medical device without registration of retail of medical devices.

Detailed conditions, manner of determining the fulfillment of conditions, and the content of the decision on registration of retail shall be prescribed by the Ministry.

Article 74

A specialized retail store shall carry out its activities of retail in accordance with the registration decision issued by the Agency.

A specialized shop shall meet the following requirements:

1) to have an employed person responsible for the receipt, storage, keeping, sale and dispensing of medical devices;

2) to have adequate premises and equipment;

3) to keep records on the type and quantity of sold medical devices in Montenegro, by individual packages; and

4) other conditions for retail of medical devices in accordance with this Law.

A specialized retail store shall ensure the continuous availability of persons referred to in paragraph 1 item 1 of this Article.

Article 75

Application for registration of retail shall be filed with the Agency and contains:

1) name and residence or domicile or name and seat of the legal or natural person and the place of sale and dispensing of medical devices;

2) name of the responsible person supervising the receipt, storage, sale and dispensing of medical devices;

3) a list of medical devices or a group of medical devices intended for sale and dispensing ; and

4) other information important for obtaining the authorization for retail of medical devices, in accordance with the law.

The decision on retail sale registration shall be issued for an indefinite period.

The person referred to in paragraph 1 item 2 of this Article should have the appropriate medical or technical qualifications and level of education, depending on the type and class of medical devices placed on the market.

Article 76

The provisions of Article 65 of this Law shall apply to the cessation of the validity of the decision on the registration of retail of medical devices.

Article 77

A specialized retail store and healthcare institution may dispense or sell a medical device exclusively for the needs of patients, other healthcare institutions, and specialized retail store that it supplies with medical devices under the conditions prescribed by this Law.

Article 78

The Agency shall maintain a register of medical devices, manufacturers with residence, domicile or seat established in Montenegro and manufacturers of medical devices with seat, residence or domicile outside of Montenegro, wholesalers, specialized retail stores and importers.

Detailed contents and manner of keeping registers shall be prescribed by the Ministry.

Data from registers shall be published on the Agency’s website.

Article 79

Legal and natural persons carrying out pharmacy activities in Montenegro, specialized retail stores for medical devices and wholesalers may offer medical devices for distance sale online in accordance with their activities and in accordance with the law governing internet sale.

The persons referred to in paragraph 1 of this Article shall submit the following information to the Agency:

1) name, residence or domicile and address of the place from which the medical devices are sold;

2) start date of the sales activity;

3) website address used for this purpose and all the necessary information for the identification of the website.

Article 80

The website referred to in Article 79 paragraph 2 item 3 of this Law, through which medical devices are offered for sale, shall contain the following information:

1) name and seat or name and residence or domicile of the legal, or natural person referred to in the Article 79 paragraph 1 of this Law;

2) name of the owner or responsible person;

3) contact information of the Agency;

4) a link to the website of the Agency with the data on legal and natural persons offering medical products for distance sale.

Detailed conditions for distance sale of medical devices offered online shall be prescribed by the Ministry.

Article 81

Transit of falsified medical devices shall be prohibited.

Wholesaler, pharmacy, specialized retail store, healthcare institution, healthcare professionals shall physically separate every falsified medical device from other medical devices without delay and take all measures to prevent it from being placed on the market again.

The entities referred to in paragraph 2 of this Article shall inform the Ministry, the Agency and the manufacturer without delay about the marketing of a medical device for which there is a reasonable suspicion that it is falsified.

Article 82

Legal and natural persons, conformity assessment body, as well as any person (distributor, supplier, carrier, postal operator, holder of a customs warehouse) who in the course of their activities come into possession of a medical device in any manner, shall ensure that their transport, storage and keeping is carried out in accordance with the instructions stated on the packaging of the medical device for transport and the conditions prescribed by this Law.

Transport and handling of medical devices in the territory of Montenegro shall be the responsibility of the manufacturer, i.e. the person registered for wholesale and retail of medical devices.

Article 83

The manufacturer, wholesaler, pharmacy and specialized retail store shall submit a report on the manufacturing, stocks, and the volume of sales for all individual medical devices (by packaging) in Montenegro at the request of the Ministry or the Agency.

The report referred to in paragraph 1 of this Article shall constitute a business secret, and the processed data shall be available to the public.

The contents of the report referred to in paragraph 2 of this Article, the period for which it is submitted, and the method of submitting the report shall be prescribed by the Ministry.

Article 84

Medical devices, starting substances, as well as other materials used in the process of manufacturing and wholesale of medical devices, which have passed their shelf life or for which a defect has been found with respect to their prescribed quality, as well as medical devices whose marketing is prohibited i.e. which have been withdrawn from the market under the conditions

prescribed by this Law and which are considered to be waste, must be destroyed in accordance with the law governing waste disposal.

A medical device manufacturer, wholesaler, specialized retail store and other retailers selling medical devices shall arrange medical devices disposal in accordance with the law governing waste disposal.

VIII LABELLING OF MEDICAL DEVICE

Article 85

Every medical device that is placed on the market shall be labelled with data for its safe and proper use.

The data referred to in paragraph 1 of this Article shall also be contained in the instructions for use of the medical device.

The packaging of the medical device shall contain the information on the manufacturer, the data necessary for the identification of the medical device and the content of the packaging, the necessary labels such as ,,sterility", ,,single use", ,,custom-made", ,,for clinical investigation" and similar, identification code, expiry date, conditions of storage, special method of use, if required, warnings, intended purpose and other necessary data of importance for the protection of health.

Data for the safe use of a medical device shall be indicated on the medical device itself and/or the packaging of each individual part, when feasible and appropriate, or on the sales package when appropriate.

If labelling referred to in paragraph 4 of this Article, is not feasible on the individual packaging of each part of a medical device, the information shall be given in the instructions for use accompanying one or more products.

Article 86

Instructions for use of a medical device, in addition to the data referred to in Article 85 paragraph 1 of this Law, shall contain information on adverse effects of the medical device, information on the method of installation and verification of proper use, as well as other necessary information on the medical device.

The instructions for use shall be placed in the packaging of each medical device.

Exceptionally, the instructions for use shall not be required for class I or IIa medical devices, in justified cases, for *in vitro* diagnostic medical devices, if they can be safely used without the instructions for use.

The instructions for use of a medical device shall be written in Montenegrin language and in languages that are in official use in Montenegro in accordance with the registration, and shall correspond in their entirety to the original text of the manufacturer's instructions and be prepared in a way that is understandable to the patient and user.

Article 87

The manufacturer shall clearly state the intended purpose of the medical device on the packaging of the medical device and in the instructions for use.

If it is rational and feasible, the medical device and its constituent parts shall be labeled with the batch number, in order to enable all necessary measures in case potential risks of a medical device and its constituents are identified.

Article 88

The inner and outer packaging of a medical device for professional use shall be labeled in Montenegrin language and in the languages that are in official use in Montenegro.

Notwithstanding paragraph 1 of this Article, the outer packaging of a medical device for professional use may be labeled in English, with a label containing all the information contained on the original packaging.

The outer packaging of a medical device that the patient uses independently shall be labeled in Montenegrin language and in the languages that are in official use in Montenegro.

Notwithstanding paragraph 3 of this Article, the outer packaging of a medical device may be labeled with a label containing all the information contained in the original packaging.

The information on the manufacturer or the authorized representative of the manufacturer of the medical device and the number of the decision on registration of the medical device shall be stated on the outer packaging and may be indicated on the label that is placed on the outer packaging of the medical device.

Affixing of the label referred to in paragraph 4 of this Article shall not be considered part of the medical device manufacture.

The Ministry shall prescribe detailed content and the manner of labeling a medical device and the contents of the instructions for use of a medical device.

Article 89

In order to prescribe a medical device for use that is not listed in the information labeled on the medical device and the information in the instructions for use, a doctor of the appropriate specialty shall ensure that the following conditions have been fulfilled beforehand:

1) that the ethics committee of the healthcare institution in which the patient is treated has given the opinion that the use of the medical device is necessary, that all other therapeutic options have been exhausted, and that there are no ethical obstacles to the use of that medical device in accordance with the appropriate treatment protocol;

2) that he has concluded based on expert and scientific knowledge that this medical device is safe and appropriate for the patient;

3) that he has sufficient evidence based on the experience on the safety and performance of the medical device for that medical indication;

4) that he takes over the responsibility for prescribing the medical device and monitoring the patient’s treatment;

5) that he keeps clear, precise and accurate records of the medical devices prescribed for use that is not listed in the information marked on the medical device and the information in the instructions for use, in the medical dossier of the patient with specified medical reasons for prescribing that medical device, in accordance with the law.

IX CLINICAL INVESTIGATIONS

Article 90

Clinical investigation shall be carried out in accordance with the guidelines of Good Clinical Practice in clinical investigation, i.e. the standard for clinical investigation of medical devices of the International Organization for Standardization (ISO 14155).

The safety and performance of *in vitro* diagnostic medical device shall be assessed based on clinical performance assessment studies.

Guidelines for Good Clinical Practice shall be published on websites of the Ministry and the Agency.

Article 91

Clinical investigation of a medical device may be carried out only in cases where the benefit from use of investigational medical device is higher then its potential risks for subjects and other and future patient life and health, based on opinion is given by the Ministry and the Agency.

The proposal of the opinion referred to in paragraph 1 of this Article shall be submitted to the Ministry by the Ethics Committee for Clinical Investigation of Medical Devices (hereinafter: the Ethics Committee), which shall be established by the Ministry as a professional and advisory body.

The Ethics Committee is an independent expert body consisted of medical experts and non-medical experts.

Ethics Committee shall give the opinion on:

1) clinical investigation protocol;
2) the acceptability of the investigator;
3) the acceptability of the conditions, methods and documents to be used to inform the subjects and obtain their informed consent in a transparent manner;
4) non-commercial clinical investigation;
5) significant, substantial amendments to the clinical investigation; and
6) ensuring the protection of the rights, safety and well-being of the subjects participating in clinical investigation.

Detailed manner of operating and decision making of the Ethics Committee shall be prescribed by the Ministry.

Article 92

Clinical investigation of a medical device can be carried out by a sponsor who has an authorization issued by the Agency.

Clinical investigation of a medical device shall be carried out at the healthcare institution at the expense of the sponsor.

A sponsor who has no seat, residence or domicile in Montenegro, must have a representative in Montenegro, who is responsible for sponsor affairs in the procedures for approving and conducting clinical investigations in Montenegro.

Article 93

Sponsor of a clinical investigation may transfer all or part of its responsibility to another natural or legal person by way of a contract, but this does not relieve it of the responsibility for the clinical investigation of the medical device.

An application for clinical investigation of a medical device, including a non-commercial clinical trial, may be submitted to the Ethics committee and the Agency at the same time.

Detailed contents of the application, the documentation necessary for the conduct of a clinical investigation, or the recording of non-interventional investigation, as well as basic requirements for clinical evaluation shall be prescribed by the Ministry.

Article 94

The Agency shall issue an authorization for clinical investigation of a medical device within 40 days from the date of receipt of a full application with the documentation, including the positive opinion of the Ethics committee.

If the application referred to in paragraph 1 of this Article is not complete, the Agency shall notify the applicant within 10 days from the date of receipt of the application to complete the application no later than 20 days from the date of receipt of the notification.

The time limit referred to in paragraphs 1 and 2 of this Article shall not run until the submission of additional documentation or additional explanation at the request of the Agency.

If the applicant fails to supplement the application for authorization of conducting a clinical investigation within the time limit referred to in paragraph 2 of this Article, the Agency shall reject the application as incomplete.

Article 95

The sponsor shall inform the Ethics committee and the Agency of any administrative and of any significant, substantial amendments to the clinical investigation.

The Ethics committee and the Agency shall give their opinions on any significant, substantial amendments to the clinical investigation within 30 days from the date of receipt of the full application.

If the application referred to in paragraph 1 of this Article is incomplete, the Agency shall inform the applicant within a period of five days from the date of receipt of the application that it should supplement the application no later than ten days from the date of receipt of the notification.

The deadline for the approval of significant, substantial amendments to the clinical investigation shall not run until the required information is supplied.

If the applicant fails to submit the requested data within the deadline referred to in paragraph 3 of this Article, the Agency shall reject the application for the approval of significant, substantial amendments to the clinical investigation as incomplete.

Applicant for the clinical investigation of a medical device may introduce significant, substantial amendments after obtaining a positive opinion of the Ethics committee, as well as when the Agency fails to deliver the opinion within the deadline referred to in paragraph 2 of this Article.

Article 96

The Agency shall reject the application for authorization of conducting a clinical investigation if it establishes:

1) that the benefit of the medical device that is clinically investigated is lower than its potential risk to the life and health of the subjects;

2) that the quality of the medical device has not been confirmed and that the non-clinical investigations have not been completed;

3) that the documentation submitted is not compliant with the conditions prescribed by this Law.

Article 97

Clinical investigation of a medical device can be carried out only with the informed consent of the subject being investigated.

In exceptional cases, if the person is incapacitated of giving informed consent or is underage, the consent shall be signed by the legal representative or guardian after being informed of the risks and objectives of the investigation.

If the subject is illiterate or unable to write, he shall give oral consent in the presence of at least one witness who is not a member of the team of investigators.

Subjects referred to in paragraphs 1 and 2 of this Article may, at any time, withdraw the informed consent to participate in a clinical investigation.

Clinical investigation must not be conducted on prisoners, or on persons who could be influenced by coercion to give consent for participation in a clinical investigation.

Article 98

Clinical investigation of a medical device shall be carried out with respect of the principles of medical ethics and the mandatory protection of privacy and personal data of the subjects in accordance with the guidelines for Good Clinical Practice and the law governing personal data protection.

Clinical investigation of a medical device shall be carried out within healthcare institution referred to in Article 92 paragraph 2 of this Law, who has concluded a contract on clinical investigation of the medical device with the clinical investigation sponsor or applicant.

The contract referred to in paragraph 2 of this Article shall specify the total costs of conducting the clinical investigation, the expenses borne by the sponsor, including the costs of medical and other services of the healthcare institution, as well as the fees for the investigators and subjects.

The sponsor shall insure subjects before the start of the clinical investigation against liability in case of harm related to the clinical investigation and which corresponds to the purpose, nature and scope of the risk, in accordance with the law governing the insurance.

Policy insurance must be valid during the whole course of the clinical investigation.

The fees for the investigators and subjects referred to in paragraph 3 of this Article shall be paid by the sponsor to the healthcare institution to which it has concluded a contract on the clinical investigation.

Article 99

The sponsor shall notify the Agency on the clinical investigation that has been completed according to the investigation plan, within one year from the clinical investigation completion date.

The report on the completed clinical investigation shall be submitted to the Agency within one year from the end of the clinical trial.

If a clinical investigation has been completed before the deadline specified in the clinical investigation plan or has been suspended, the sponsor shall notify the Agency within 15 days from the day of suspension of the clinical investigation, with a detailed explanation of the cause.

Article 100

The Agency shall authorize the conducting of post-market interventional clinical follow-up in accordance with this Law.

The provisions of Articles 90 to 99 of this Law shall also apply to clinical investigation of a medical device for which conformity assessment has been carried out, if the intended purpose of that investigation is the use of the medical device for an intended purpose not covered by the corresponding conformity assessment procedure.

Article 101

Sponsor shall report the implementation of a post-market non-interventional clinical follow-up to the Agency.

The authorization of the Agency shall not be required for the clinical investigation referred to in paragraph 1 of this Article.

The Agency shall issue a confirmation of receipt of the application referred to in paragraph 1 of this Article within 15 days from the date of its receipt.

Article 102

If a serious adverse event occurs in the course of a clinical investigation, the sponsor shall immediately notify the Agency and the Ethics committee.

The Agency may propose to the Ministry to suspend or prohibit the conduct of a clinical investigation in cases referred to in paragraph 1 of this Article, in particular if it is established that there was a non-compliance with the procedures in the clinical investigation protocol or the guidelines for Good Clinical Practice.

The Ministry shall suspend or prohibit the conduct of the clinical investigation referred to in paragraphs 1 and 2 of this Article based on inspection carried out in accordance with the law governing inspection surveillance.

In case of adverse events that require application of emergency safety measures, the sponsor may instruct the investigator to apply these measures without the prior approval of the Agency.

Sponsor shall inform the Agency of the occurrence of adverse events referred to in paragraph 4 of this Article without delay and at the latest within seven days from the date of application of the safety measures.

Article 103

During the development and manufacture of an investigational medical device, the preparation of the clinical investigation documentation, as well as during the conduct of the clinical investigation, the sponsor and investigators shall comply with the Good Clinical Practice, principles and standards prescribed by the relevant EU guidelines, in addition to the conditions prescribed by this Law.

Article 104

The control of the compliance of a clinical investigation with the protocol, Good Clinical Practice guidelines, and latest updated version of the EU guidelines relating to clinical investigation in accordance with this Law shall be carried out by the Agency and it shall undertake the measures necessary for the protection of public health.

The control referred to in paragraph 1 of this Article shall be carried out:

1) at the places where the clinical investigation is carried out;
2) at the place of manufacture of the investigational medical device;
3) at the location of the sponsor and contracting parties;
4) in laboratories where analyses for clinical investigation are carried out.

The Agency shall carry out the control of the compliance of clinical investigation:

1) as part of the procedure for registering a medical device in the medical device register;
2) during the period of validity of the decision on the entry of a medical device into the register of medical devices;
3) on the territory of Montenegro (before the start, during and after the completion of the clinical investigation).

Article 105

The Agency may also exercise control at the request of a sponsor.

The Agency may accept the control of a clinical investigation conducted by an EU Member State in accordance with the Good Clinical Practice guidelines or another country with the same requirements for conducting clinical investigations as in Montenegro.

Article 106

Prior to the commencement of the control of the conduct of clinical investigation, the Agency shall inform the sponsor and the principal investigator on the control of the clinical investigation.

The Agency shall submit a report to the applicant referred to in the Article 105 of this Law on the control of the conduct of the clinical investigation carried out.

Article 107

In the process of controlling the conduct of clinical investigation, the Agency may order the applicant in writing to rectify certain irregularities in the conduct of the medical device clinical investigation within 60 days from the day of the notification.

The Agency may suspend or prohibit the conduct of a clinical investigation if irregularities are not rectified within the deadline referred to in paragraph 1 of this Article and if it establishes that the conduct of the e clinical investigation is not carried out in accordance with the protocol or Good Clinical Practice guidelines and this Law.

Article 108

The Agency may suspend or prohibit the conduct of clinical investigation for which it has issued an authorization for the conduct of clinical investigation, if this is in the interest of protecting the health and safety of subjects involved in clinical investigation, or if this is in the interest of science and the society as a whole.

If, on the basis of the control carried out, the Agency establishes that it is not necessary to urgently stop the initiated clinical investigation of the medical device it shall request additional information from the sponsor, or principal investigator on the conduct of the clinical investigation.

The clinical investigation sponsor or principal investigator shall deliver, within eight days from the day when the data referred to in paragraph 2 of this Article are requested, all the data requested to the Agency, on the basis of which the Agency shall inform the sponsor, principal investigator, the Ethics committee, or the European Commission on the proposed measures, in accordance with this Law.

Article 109

An investigational medical device shall be manufactured in accordance with the essential requirements.

The provisions of this Law that refer to the essential requirements for the manufacturing of a medical device shall also apply to manufacture of investigational medical device, unless otherwise provided by this Law.

Article 110

An investigational medical device shall be marked with the following words: „for clinical investigation”.

Article 111

Import of an investigational medical device, as well as of medicines and medical devices used in the conduct of a clinical investigation, shall be carried out by a wholesaler, based on the authorisation of the Agency for the conduct of the clinical investigation and the authorization of the sponsor.

The list of products that are used in the conduct of the clinical investigation, containing the name and the quantity of the product, shall be an integral part of the authorization for the conduct of a clinical investigation.

If the import of the products referred to in paragraph 1 of this Article differs from the list of products referred to in paragraph 2 of this Article, the wholesaler shall apply for the authorization of the importation of those products.

The Agency shall issue the authorization referred to in paragraph 3 of this Article not later than ten days after the date of submission of the application.

X VIGILANCE, MONITORING AND SURVEILLANCE OF MEDICAL DEVICES ON THE MARKET

Article 112

The Agency and the manufacturer or the authorized representative shall organize a system of vigilance with the aim of collecting and assessing data related to the safety of use of the medical device as well as other data of importance for estimating the benefit and risk ratio of using the medical device in order to protect the health of the population.

Article 113

The Agency shall provide, organize and coordinate collecting and analysis of the data obtained after medical device is placed on the market, and in particular reporting of incidents.

The Agency shall record, evaluate and undertake measures in case of an incident referred to in Article 114 of this Law.

Depending on the results of the incident investigation, the Agency shall provide information to the expert public and, if necessary, the general public, necessary to prevent incidents or to limit their consequences after the placing of medical devices on the market and putting them into service.

The Agency may require the manufacturer or its authorized representative to submit a reasoned report on the experience with the medical device on the market.

Article 114

Healthcare institutions or vigilance coordinators, healthcare professionals, manufacturer or authorized representative, wholesalers, persons involved in the delivery or putting into service of a medical device, as well as persons responsible for the calibration and maintenance of a medical device, shall inform the Agency, without delay, of a medical device incident, as follows:

1) any malfunction or alteration of the characteristics or performance of a medical device, as well as any irregularity in the labeling or instructions for use that have led or may lead to the death of a patient or user or to a serious deterioration in his state of health;

2) any technical or medical cause related to the performance of the medical device referred to in paragraph 1 of this paragraph, which is the reason for the manufacturer or the authorized representative of the manufacturer to withdraw a medical device of the same type from the market.

The entities referred to in paragraph 1 of this Article shall inform the manufacturer or the authorized representative about the medical device incident.

The Agency shall notify the administrative authority responsible for inspection affairs of the incident referred to in paragraph 1 of this Article and propose appropriate measures in accordance with this Law.

Article 115

The manufacturer, or the authorized representative, shall continuously monitor the medical device on the market in order to identify the need to immediately apply all the necessary corrective or preventive measures and shall keep records of the corrective and preventive measures implemented and inform the Agency thereof.

The manufacturer, or the authorized representative, shall notify the Agency without delay of the initiated safety corrective measure.

The manufacturer or the authorized representative of the manufacturer shall give a safety notice to all entities referred to in Article 114 of this Law.

The manufacturer or the authorized representative shall submit to the notified or designated body that has carried out the conformity assessment information on all changes arising from the system of vigilance, in case these changes affect the conformity of the medical device.

Article 116

The designated body shall monitor the system of vigilance in terms of the assessment of procedures and verification of the implementation of vigilance procedures, connection with other systems (corrective and preventive measures), assessment of the impact of vigilance on the issued certificates of conformity, and it shall carry out certain investigations, i.e. repeat the conformity assessment of vigilance procedures at the request of the Ministry.

Article 117

Technical evaluation of a medical device on the market shall be carried out by testing and controlling samples of medical devices:

1) taken by the method of random selection from the market;

2) by testing or controlling a sample of a medical device in the event of a reported quality defect, as well as a medical device suspected of being falsified.

Control of medical devices shall be carried out based on risk analysis, probability of occurrence of harmful consequences, vigilance data, data obtained in the medical device market surveillance and conformity assessment of the medical device labeling, as well as other data.

Control shall be carried out at the request of the authority in charge of inspection affairs in order to resolve the reported suspicion of quality defect of the medical device, or the suspicion that the medical device has been falsified.

In case of suspicion of non-conformity of a medical device with the basic safety requirements, sampling of that medical device shall be carried out and the testing or conformity assessment.

Technical evaluation on the market may be carried out by an authorized body in accordance with the applicable national or European pharmacopoeia or an international pharmacopoeia, by conducting physical, chemical, biological and microbiological tests.

In the process of technical evaluation referred to in paragraph 5 of this Article, the Agency may request the manufacturer to provide, within 30 days at the latest, the necessary quantity of samples, analytical methods and reference standards, i.e. operating standards necessary for conducting the analytical procedure of the manufacturer.

For the tests referred to in paragraph 1 of this Article, the manufacturer shall provide, upon the order of the Agency, a proof of the technical evaluation carried out by the authorized body or accredited laboratory of the EEA, or a country with which the European Commission has concluded a contract on mutual recognition of conformity assessment procedures in case there is no authorized body in Montenegro with the scope of accreditation covering the necessary tests referred to in paragraph 1 of this Article.

If the authorized body establishes non-conformity with the essential requirements, i.e. a quality defect of the medical device, it shall notify the Ministry without delay.

The cost of testing and verification of product conformity and other costs related to the inspection control incurred during the surveillance shall be borne by the holder of the medical device registration or the importer for a medical device referred to in Article 66 of this Law, if it is found that the medical device is not compliant with the essential requirements.

For a medical device for which it is established that there is no quality defect or that it complies with the essential requirements, the costs referred to in paragraph 9 of this Article shall be borne by the legal or natural person who submitted the application for control to the administration authority in charge of inspection affairs or the Agency.

Article 118

After the technical evaluation referred to in Article 117 of this Law is carried out, the authorized body shall issue a certificate of analysis, i.e. a confirmation of the technical evaluation carried out within 30 days from the date of submission of the complete application.

Detailed method of technical evaluation, types of quality defects and the manner of taking action in case of deviation from the essential requirements, i.e. quality defect of a medical device, as well as the manner of issuing and the content of the analysis certificate referred to in paragraph 1 of this Article, shall be prescribed by the Ministry.

Article 119

In order to provide the vigilance system, the Agency shall cooperate with the competent authorities of the EEA countries and the European Commission as well as with EUDAMED, CAMD, the World Health Organization, competent authorities of other countries responsible for public health or occupational diseases, notified and designated bodies, health insurance funds, professional associations, distributors, as well as other bodies that possess data on the risk associated with a medical device.

Detailed manner and procedure for monitoring a medical device and the system of vigilance on the market shall be prescribed by the Ministry.

Article 120

If is the Agency establishes that a medical device that complies with the essential requirements or a custom-made medical device, when properly installed, maintained and used in accordance with its intended purpose, may endanger the health and/or safety of the patient, user or of another person, it shall propose to the administration authority responsible for inspection affairs prohibition or

restriction of placing on the market and/or putting into service or to order withdrawal from the market in accordance with this Law and the law governing inspection affairs.

The administrative authority responsible for inspection affairs shall immediately inform the Ministry and Agency about of taken measures.

Article 121

If the Agency determines that the medical device referred to in Article 120 paragraph 1 of this Law presents an unacceptable risk to public health or the safety of patients, users, or other persons and also if it does not meet conditions prescribed by this Law, it shall without delay inform the manufacturer to take all appropriate preventive and/or corrective measures or to withdraw medical device from the market.

Article 122

The importer of the medical device, as well as the person responsible for vigilance within the importer, shall be responsible for the withdrawal of the medical device referred to in Article 66 of this Law from the market and for undertaking measures not to put it onto the market.

If the manufacturer, wholesaler or importer decides to withdraw from the market a medical device or a specific medical device batch, it shall immediately inform the Agency.

Article 123

The Agency shall publish on its website a notification on the measures and activities to be taken in relation to the serious risk that the medical device poses for public health and user safety.

Detailed conditions for the procedure of suspension or withdrawal of a medical device from the market, as well as the deadlines and manner of notification of suspension and withdrawal shall be prescribed by the Ministry

XI ADVERTISING OF MEDICAL DEVICES

Article 124

Advertising of a medical device is any form of providing truthful information about the medical device to the general and professional public by the manufacturer, as well as by a legal or natural person who carries out the marketing of medical devices, in order to encourage the prescription and supply of medical devices, their sales and consumption.

Advertising of a medical device as referred to in paragraph 1 of this Article shall include:

1) advertising of medical devices via means of public informing, including the Internet, advertising in public places and other forms of advertising of medical devices (by mail, visits, etc.);
2) promotion of medical devices to healthcare professionals who prescribe medical devices or who use medical devices, by informing them at expert events, in professional journals and other forms of promotion;
3) giving free samples to the expert public;
4) sponsoring scientific and promotional events in which the professional public participates (covering the necessary expenses for travel, accommodation, food, as well as the cost of compulsory participation in scientific and promotional events);

5) encouraging the prescribing and dispensing of medicines, by giving or promising financial, material or other benefits.

Indicating the name of a medical device, the description of a medical device, or the trademark shall not be considered as advertising if it serves exclusively as a reminder.

Article 125

Advertising of a medical device shall be in accordance with this Law, technical requirements, as well as the instructions for use of the medical device from the manufacturer.

Article 126

Advertising of a medical device to the expert public shall contain basic data on the medical device that must be accurate, updated, verifiable and in sufficient in detail so that the recipient can form their opinion on a particular medical device on the basis of such data, and shall indicate the date when they were composed or when they were last revised.

Giving of a medical device is permitted only to the professional public in order to inform them about the characteristics of the medical device being placed on the market, with a note on the package: „Free sample, not for sale".

Article 127

Advertising of a medical device to the general public shall include the advertising of a medical device intended for use by a patient, whose advertising is not prohibited by law, through means of public informing, the Internet, advertising in public places, as well as other forms of advertising to the general public (delivery of advertising material by mail, visits etc.).

Information advertised about a medical device shall be true and scientifically proven and must not mislead the professional and general public.

The information referred to in paragraph 2 of this Article shall be given for the purpose of proper and rational use of a medical device while complying with ethical standards.

Advertising of a medical device to the general public must not be exclusively or primarily directed at children.

In the advertising of a medical device to the general public, it is not permitted to show children taking the medical device, or children to whom the medical device is available without the presence of adults.

In advertising of a medical device to the general public, it is not permitted to make allegations or conclusions about the efficacy of a medical device that is the subject of clinical investigation in the country or abroad.

Free samples of only that medical device that can also be sold in other places other than in health institutions and specialized shops, as well as the medical device used during the implementation of preventive programs or health promotion campaigns, may be given free of charge in accordance with the law.

Article 128

Medical device manufacturers, representatives of manufacturers and legal persons who carry out marketing of medical devices shall not offer financial, material or other benefit to persons who prescribe or issue medical devices as well as members of their families.

Notwithstanding paragraph 1 of this Article, manufacturers, authorized representatives and legal entities that carry out the marketing of medical devices may be sponsors of scientific and

promotional events in which the expert public participates, by covering the necessary expenses for travel, accommodation, food, as well as the costs of compulsory participation at scientific and promotional events.

Article 129

Advertising of medical devices that are dispensed at the expense of health insurance shall be prohibited.

Advertising of a medical device that is not compliant with the technical requirements or that is not registered shall be prohibited.

Advertising of a medical device that misleads, i.e. which describes the disease and the success of treatment in a way to induce self-healing, as well as advertising of a medical device in an inappropriate and sensational manner about their success in treatment by displaying pictures, etc. shall be prohibited.

In order to protect public health, the Ministry may also prescribe other medical devices that cannot be advertised.

Detailed conditions and manner of advertising of medical devices shall be prescribed by the Ministry.

XII INSPECTION CONTROL

Article 130

The Ministry shall carry out surveillance of the implementation of this Law and the regulations adopted pursuant to this Law, unless otherwise prescribed by this Law.

Inspection surveillance shall be carried out by healthcare inspectors pursuant to this Law and law governing inspection affairs, health inspection, health protection and health insurance.

Article 131

In the inspection surveillance procedure, the administrative authority in charge of inspection affairs shall assess the conformity of the medical device manufacture, wholesale and retail of medical devices in accordance with this Law and the law governing inspection affairs.

If it determines a critical non-conformity, the administrative authority in charge of inspection affairs shall immediately take all necessary measures for the protection of public health.

If it determines a critical non-conformity that may affect the quality of the medical device on the market, the administrative authority in charge of inspection affairs may ask for an extraordinary conformity assessment of the medical device sampled from wholesale or retail by relevant designated or authorized body.

The costs of conformity assessment referred to in paragraph 3 of this Article shall be borne by the wholesaler.

In the case of determining minor non-conformities in the performance of the activities referred to in paragraph 1 of this Article, the administrative authority in charge of inspection affairs may order a measure of eliminating the non-conformity and issue an order to the entities referred to in paragraph 1 of this Article to eliminate the identified non-conformities within 30 days at the latest.

When the administrative authority in charge of inspection affairs establishes a critical non-conformity of production or trade of a medical device, it shall undertake measures and inform the Agency because of removal from the register.

Article 132

The administrative authority in charge of inspection affairs shall control the investigation of an incident carried out by the manufacturer or the authorized representative and take measures necessary to amend the measures taken by the manufacturer, or the authorized representative.

Article 133

The administrative authority in charge of inspection affairs shall prohibit marketing and issue an order to withdraw a medical device or a particular medical device batch from the market in cases referred to in Article 7 of this Law as well as:

1) if a particular medical device is harmful under the usual conditions of use, on the proposal of the Agency or on the basis of a notice received from the designated body;

2) if it fails to fulfill its performance, on the proposal of the Agency or on the basis of a notice received from the designated body;

3) if the risk-benefit ratio is not favorable under the approved conditions of use, on proposal of the Agency;

4) if its qualitative and quantitative composition does not correspond to the declared one;

5) if the prescribed conformity assessment procedures were not carried out by the designated body; and

6) in other cases when a medical device is on the market contrary to the conditions prescribed by this Law.

The administrative authority in charge of inspection affairs may order the withdrawal of a medical device or a certain batch of medical device from the market, on the basis of a notice obtained through the international system for the rapid exchange of information on unsafe products of the EU, the EEA and the state with which the EU has concluded a Mutual Recognition Agreement (MRA), from the authorities or institutions of these countries in charge of medical devices, the Pharmaceutical Inspection Cooperation Scheme (PIC/S), if the notice contains a proposal for measures and actions to be taken in relation to the serious risk that the medical device poses for public health and the safety of the users.

The administrative authority in charge of inspection affairs shall inform the Agency on taken actions referred to in paragraphs 1 and 2 of this Article.

Article 134

In addition to obligations and responsibilities determined by the law governing the inspection affairs, the inspector referred to in Article 130 paragraph 2 of this Law while performing the inspection is authorised to:

1) review general and individual acts, records, contracts, technical documentation and other documentation related to the manufacturing, marketing, labelling, declaration of conformity, investigation and quality control, as well as the documentation relating to the implementation of guidelines of Good manufacturing practice, Good laboratory practice and Good distribution practice
2) have immediate insight into the implementation of Good manufacturing practice and Good distribution practice, as well as standard and operational procedures in these areas;
3) inspect personal documents of the personnel with the purpose of identification;
4) hear and take statements from responsible and interested persons;
5) inspect business premises, facilities, installations, machines, equipment;
6) inspect medical devices, labelling, marking of conformity, instructions for use, expiry dates;

7) take copies of the reviewed documents with stating in the minutes;
8) take samples of medical devices with the purpose of determining quality;
9) take photos or record data on the personnel, facility, equipment, machines, etc. with the purpose of data collecting.

Article 135

In addition to the administrative measures and actions established by the law governing inspection surveillance, inspectors referred to in Article 130 paragraph 2 of this Law, when establishing non-compliance with the requirements set out in this Law and other regulations shall have the authority and obligation to:

1) order the performance of activities in accordance with the conditions laid down in this Law and other regulations;
2) order elimination of identified irregularities and deficiencies within a specified period;
3) prohibit the implementation of actions that are contrary to this law and regulations for its implementation;
4) temporarily prohibit the work of a legal or natural person if it does not meet the requirements in terms of personnel, equipment, devices and premises;
5) prohibit work of a legal person if it is engaged in investigation, manufacturing, marketing, brokering, checking of the quality of a medical device without the approval or authorization of the Agency;
6) prohibit placing on the market if:
   -medical device is falsified,
   -validity period of a medical device has expired,
   - it is determined that the medical device is improperly stored or handled,
   - a medical device has no marketing authorization;
7) suspend the marketing of a medical device, or its batch, that does not meet the conditions prescribed by this Law;
8) order the withdrawal of a medical device or its batch from the market in the cases prescribed by this Law;
9) order the destruction of a medical device in accordance with this Law;
10) suspend or prohibit conducting of a clinical investigation if it is conducted contrary to this Law and the regulations adopted for its implementation, at the proposal of the Agency, or ex officio;
11) prohibit advertising of a product to which medical indications are attributed, and it is not a medical device within the meaning of this Law;
12) submit a proposal for revocation of the authorisation for placing a medical device on the market if the holder of the authorization does not have an organized system of vigilance, responsible person for vigilance or does not fulfill other obligations regarding vigilance prescribed by the provisions of this Law;
13) prohibit work and submit a proposal to the Agency for revocation of the authorisation for performing activities if the conditions prescribed by this Law and the regulations for its implementation are not fulfilled.

XIII PENAL PROVISIONS

Article 136

A fine in the amount of 1,000 to 20,000 EUR shall be imposed on a legal entity for an offence if it:

1) fails to implement the sterilization process of medical devices with the marking of conformity for which the manufacturers have stated that they must be sterilized before use in accordance with the appropriate quality system and does not compose a statement indicating that sterilization is conducted in accordance with manufacturer instruction for use(Article 20 paragraph 1);
2) fails to implement arrangements ensuring safety and efficacy and whose level of requirements is at the level of the common technical specifications, if, for justified reasons, *in vitro* diagnostic medical device does not meet the common technical specifications (Article 25 paragraph 4);
3) fails to submit an application to the Ministry prior to the commencement of the activity in order to obtain a decision on authorization or designation in accordance with this Law and law governing the field of technical requirements for products and conformity assessment, while conducting medical device conformity assessment and carrying out technical assessment activities while (Article 31);
4) within the conformity assessment procedure does not take into account, the results of all assessment and verification procedures carried out in accordance with this Law, where applicable (Article 34, paragraph 2);
5) establishes that the essential requirements are not fulfilled or that the manufacturer no longer fulfills them or that the certificate should not have been issued, , in relation to the type and scope of non-conformity, does not suspend, withdraw or limits certificate, unless the manufacturer ensures compliance with the essential requirements by applying the appropriate corrective measures. (Article 34 paragraph 6);
6) fails to manufacture medical devices in accordance with the essential requirements and decision issued by the Agency. (Article 54 paragraph 1);
7) fails to provide conditions in terms of space and equipment for the medical devices manufacture, in accordance with the essential requirements for the medical device of which manufacture is carried out (Article 54 paragraph 2 item 1)
8) fails to provide at least one person responsible for the manufacture (Article 54 paragraph 2 item 2)
9) fails to provide at least one person responsible for the quality and vigilance (Article 54 paragraph 2 item 3)
10) fails to ensure that the medical device is designed in accordance with the essential requirements (Article 54 paragraph 2 item 4)
11) fails to classify the medical device in the appropriate risk class, prepare the prescribed technical documentation and implement, or ensure the implementation of the applicable conformity assessment procedure (Article 54 paragraph 2 item 5);
12) fails to issue a declaration of conformity, where applicable, and mark the medical device with a marking of conformity in accordance with this Law (Article 54 paragraph 2 item 6)
13) fails to have in place procedures ensuring maintenance of conformity of the medical device manufacturing with the essential requirements and technical standards (Article 54 paragraph 2 item 8);

14) fails to take the necessary corrective measures in the event of established non-conformity (Article 54 paragraph 2 item 10);
15) for a medical device, except for a custom-made medical device or investigational medical device, fails to establish and maintain monitoring plan for medical device after its putting on the market, and fails to keep proper records of non-compliant medical devices and those withdrawn from the market (Article 54 paragraph 2 item 11);
16) fails to provide insurance against harmful effects that may arise when using a medical device, in accordance with the Insurance Law (Article 54 paragraph 3);
17) fails to provide continuous availability of persons responsible for manufacturing, quality and vigilance Article 55 paragraph 1);
18) fails to continuously supply the market with medical devices from its program in accordance with the decision on the registration of medical devices (Article 57)
19) fails to submit an application to the Agency for removal from the register of manufacturers and removal from the register of medical devices within 30 days from the expiration date or the cancellation of the decision (Article 60 paragraph 1)
20) fails to carry out wholesale of medical devices in accordance with the decision on wholesaler registration and in accordance with the guidelines for Good Distribution Practice of medical devices (Article 63 paragraph 1);
21) fails to ensure continuous supply of the market with medical devices in accordance with the decision on wholesaler registration (Article 70 paragraph 1)
22) upon request of a healthcare institution, specialized retail store, and other organization authorized to provide healthcare in accordance with the law, fails to deliver the medical device for which it has received the wholesaler registration and which is entered in the register of medical devices as soon as possible (Article 70 paragraph 2)
23) fails to provide the necessary stocks of medical devices for the wholesale of which it has been registered and which are entered in the register of medical devices, i.e. start procurement or import in a timely manner in order not to interrupt the supply of the market (Article 70 paragraph 3)
24) fails to arrange disposal of medical devices in accordance with the law governing waste disposal (Article 84 paragraph 2)
25) fails before the start of the clinical trial to insure subjects against liability in case of harm related to the clinical trial and which corresponds to the purpose, nature and scope of the risk, in accordance with the law governing insurance.
26) fails to immediately notify the Agency and the Ethics committee if there is a serious adverse event during the conduct of a clinical trial (Article 102 paragraph 1 item 1);
27) fails to organize a system of vigilance with the aim of collecting and assessing data related to the safety of use of the medical device as well as other data of importance for estimating the benefit and risk ratio of using the medical device in order to protect the health of the population Article 112)
28) fails to inform the Agency, without delay, of a medical device incident involving malfunction or alteration of the characteristics or performances of a medical device, as well as any irregularity in the labeling or instructions for use that have led or may lead to the death of a patient or user or to a serious deterioration in his state of health (Article 114 paragraph 1 item 1);
29) fails to inform the Agency, without delay, of a medical device incident involving any technical or medical cause related to the performance of the medical device referred to in

paragraph 1 of this paragraph, which is the reason for the manufacturer or the authorized representative of the manufacturer to withdraw a medical device of the same type from the market (Article 114 paragraph 1 item 2);

30) fails to continuously monitor the medical device on the market in order to identify any need to immediately apply all necessary corrective or preventive measures and/or fails to keep records on corrective and preventive measures taken (Article 115 paragraph 1);
31) fails to submit information on all changes arising from the system of vigilance, in case these changes affect the conformity of the medical device, to the notified body or the designated body that carried out the conformity assessment (Article 115 paragraph 4);

For an offence referred to in paragraph 1 of this Article, a responsible person in a legal person shall also be fined to the amount of EUR 250 to EUR 2,000.

For an offense referred to in paragraph 1 of this Article, natural person shall be fined to the amount of EUR 250 to EUR 2,000.

In addition to the penalty for the offence referred to in paragraph 1 of this Article, a safeguard measure of prohibition of pursuit of activity for a period up to 6 months may also be imposed.

Article 137

A fine to the amount of EUR 2,500 to EUR 10,000 shall be imposed on a legal entity if it:

1) fails to keep the declaration i.e. document of conformity, technical documentation prescribed by this Law, as well as the decisions, reports and certificates issued by the conformity assessment body, and fails to make them available to the administrative authority in charge of inspection affairs for a period of five years, and in the case of implantable medical devices, for at least 15 years from the date of manufacture of the last medical device (Article 27);
2) fails to notify the Ministry and the Agency of all issued, amended, suspended, withdrawn, restricted or refused certificates (Article 34 paragraph 3);
3) fails to notify other conformity assessment bodies designated in accordance with this Law of any certificates suspended, withdrawn or refused, and upon request the manufacturer (Article 34 paragraph 4);
4) fails to place a medical device on the market within 12 months from the date of delivery of the decision referred to in the Article 42 paragraph 3 of this Law in accordance with that decision, i.e. submission referred to in the Article 42 paragraph 4 of this Law (Article 45);
5) fails to keep the technical documentation and the declaration of conformity after placing the medical device on the market for at least five years, and for implantable medical devices for at least 15 years (Article 54 paragraph 2 item 7);
6) fails to label the medical device and attach the instructions for use in accordance with this Law (Article 54 paragraph 2 item 9);
7) fails to have a plan for the withdrawal of a medical device from the market (Article 54 paragraph 2 item 12);
8) fails to keep records on the type and quantity of sold medical devices in Montenegro (Article 54 paragraph 2 item 13);
9) fails to notify the Agency without delay of all significant changes in terms of personnel, space, or storage location of medical devices and equipment, as well as the outsourced activities (Article 72 paragraph 1 item 1);
10) fails to notify the Agency without delay of any incident that could affect the quality of the medical device or its safe handling (Article 72 paragraph 1 item 2);

11) fails to inform the Agency without delay on any problem in ensuring the continuous supply of the market with a medical device (Article 72 paragraph 1 item 3);
12) fails to physically separate every falsified medical device from other medical devices without delay and fails to take all measures to prevent it from being placed on the market again (Article 81 paragraph 2);
13) fails to clearly state the intended purpose of the medical device on the packaging of the medical device and in the instructions for use (Article 87 paragraph 1);
14) fails to inform the Ethics committee and the Agency of any administrative and of any significant, substantial amendments to the clinical trial of the medical device (Article 95 paragraph 1);
15) fails to notify the Agency without delay of the initiated safety corrective measure (Article 115 paragraph 2).

For an offence referred to in paragraph 1 of this Article, a responsible person in a legal person shall also be fined to the amount of EUR 500 to EUR 2,000.

For an offence referred to in paragraph 1 of this Article, natural person shall be fined to the amount of EUR 500 to EUR 2,000.

XIV TRANSITIONAL AND FINAL PROVISIONS

Article 138

The regulations for the implementation of this law shall be adopted within 24 months from the date of entry into force of this Law.

Until the adoption of the regulations referred to in paragraph 1 of this Article, the regulations adopted for the implementation of the law in force until the date of entry into force of this Law, which are not in conflict with the provisions of this Law, shall apply.

Article 139

The Ethics Committee referred to in Article 91 paragraph 2 of this Law shall be established by the Ministry within 90 days from the day this Law enters into force.

Article 140

Legal persons that manufacture medical devices and carry out wholesale of medical devices and retail sale of medical devices shall harmonize their operations and activities with this Law within 24 months from the date of entry into force of this Law.

Article 141

Registration of a medical device issued based on the regulations that were applicable at the time of registration shall remain in force until the expiration of the period for which they were issued.

Notwithstanding paragraph 1 of this Article, registration of medical device issued for an indefinite period of time shall be harmonized with this Law within 24 months of the entry into force of this Law.

Article 142

Procedures initiated based on applications filed to the Agency, until the date of entry into force of this Law, shall be completed in accordance with the regulations applicable at the time when the application was filed.

Article 143

The provisions of Article 37 paragraph 2, Articles 68, 69, 79 and 80 of this Law shall apply from the date of accession of Montenegro to the EU, and Article 3 and Article 25 paragraph 7 of this Law after the expiration of the transitional period of entry into force of EU regulation concerning medical devices (2017/745).

On the day of the accession of Montenegro to the EU, the provision of Article 7 paragraph 1 item 2 and Article 61 paragraph 3 of this Law shall cease to apply.

Article 144

On the day of the entry into force of this Law, the Law on Medical Devices (Official Gazette of the Republic of Montenegro No 79/04 and Official Gazette of Montenegro No 53/09) and the provision of the Article 81 paragraph 1 item 4 of the Law on healthcare protection (Official gazette of Montenegro No 3/16, 39/16, 2/17 and 44/18) shall be repealed.

Article 145

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