

Unauthorized translation

LAW ON MEDICAL DEVICES

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I INTRODUCTORY PROVISIONS

1. The subject of regulation

Article 1

This Law regulates the conditions for the manufacturing and marketing of medical devices, i.e. their placing on the market and use in the Republic of Serbia, clinical investigation of medical devices, vigilance, monitoring of medical devices on the market and technical assessment, assessment of the compliance of medical devices with essential requirements, advertising, the labelling of medical devices and supervision in this field, as well as other issues of relevance to medical devices.

The provisions of this law shall apply to medical devices for human use (hereinafter: medical devices), including *in vitro* diagnostic medical devices and active implantable medical devices.

The provisions of this Law relating to the manufacturer of medical devices shall also apply to legal and natural persons who compile the system or set, pack, make, completely renew and label one or more finished products and determine the purpose of the medical device for placing on the market of the Republic of Serbia under its own name. The provisions of this Law shall not apply to a person who, although not a manufacturer, compiles or adjusts a medical device for a specific purpose, already on the market and intended for a particular user.

The provisions of this Law shall also apply to accessory for a medical device (accessory).

The provisions of this Law shall apply to a medical device intended for the administration of a medicinal product in accordance with the law governing medicinal products, without prejudice to the provisions of the law governing medicinal products. If this medical device is placed on the market so as to make an integral product with the medicinal product intended exclusively for use in a given combination and which cannot be reused, the provisions of the law governing medicinal products shall apply to that product. The provisions of this Law shall apply to the essential requirements regarding the safety and performance of this medical device, as well as shall the regulations adopted for its implementation.

The provisions of this Law shall apply to a medical device that has a substance as an integral part which, if used separately, can be considered as a medicinal product in accordance with the law governing medicinal products and that have an action ancillary to that of the medical device.

When deciding whether the Law on Medicines shall apply to a product or this Law, special attention shall be paid to the main (primary) mode of action of the product.

The provisions of this Law shall apply to a medical device that has a substance as an integral part which, if used separately, may be considered a medicinal product consisting of human blood or human plasma or a medicinal product derived from human blood or human plasma, in accordance with the law which regulates medicinal products and which could have an effect on a human body that is ancillary to the action of a medical device (hereinafter: a human blood derivative).

The provisions of this Law shall apply to certain groups of products that the manufacturer has intended only to aesthetic or other non-medical purposes, but which are similar to the medical devices in terms of functioning and risk profile. Products that have a medical and non-medical purpose must also comply with the provisions of the law applicable to that type of products which are not intended for medical purposes.

This Law does not apply to:

- 1) Medicinal products;
- 2) Cosmetic products;
- 3) Human blood, blood products, plasma or blood cells of human origin or products containing such blood products, plasma or cells at the time of placing on the market, other than the product referred to in paragraph 8 of this Article;
- 4) Grafts, tissues or cells of human origin or derivatives thereof, nor on products containing or consisting of them, unless the medical device is manufactured by using tissue derivatives or cells of human origin which are non-viable or are rendered non-viable, as well as products from paragraph 8 of this Article;
- 5) Grafts, tissues or cells of animal origin or their derivatives or products containing or consisting of them, unless the medical device is manufactured by using tissues or cells of animal origin or derivatives thereof, which which are non-viable or are rendered non-viable;
- 6) Medical device for use solely in veterinary medicine.

2. Definitions

Article 2

Terms used in this Law, if not specified otherwise by this Law, shall have the following meaning:

- 1) Medical device (general) means any instrument, apparatus, appliance, software, implant, reagent, material and other product used alone or in combination, including software provided by the manufacturer for diagnostic or therapeutic purposes and which is software support necessary for its proper use in people intended by the manufacturer, and is used for:
 - (1) diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
 - (2) diagnosis, monitoring, treatment, alleviation or compensation of injury or disability,
 - (3) investigation, replacement or modification of the anatomy or physiological or pathological process and state,
 - (4) providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations,
 - (5) control or support of conception,
 - (6) products intended for cleaning, disinfection or sterilization of medical devices.

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

- 2) Accessory for a medical device (accessory) is a product that is not a medical device, and which the manufacturer specifically intended to use in combination with a medical device in order to enable the medical device to be used in accordance with its intended use by the manufacturer.

An invasive sampling device or one which is directly applied to the human body for the sampling is not considered *in vitro* diagnostic medical device, but is considered a general medical device;

- 3) *In vitro* diagnostic medical device is any medical device that is a reagent, reagent product, calibrator, control material, set of reagents (kit), instrument, apparatus, equipment, software or system used individually or in combination, intended by the manufacturer for use in the *in vitro* conditions for the examination of samples, including donations of blood and tissues of human origin, only or mainly to obtain information relating to:
 - (1) physiological or pathological process or state,
 - (2) congenital physical or mental anomalies,
 - (3) predisposition to a health status or illness,
 - (4) determining security and compatibility with a potential recipient,
 - (5) predicting responses or reactions to treatment,

(6) defining or monitoring therapeutic measures.

Sample receptacles are considered to be *in vitro* diagnostic medical devices. Sample receptacles are vacuum- or non-vacuum-type medical devices that the manufacturer explicitly intended for the primary keeping and storing of samples retrieved from the human body for the purpose of *in vitro* diagnostic testing.

Products for general laboratory use shall not be considered as *in vitro* diagnostic medical devices unless these products, due to their characteristics, are specifically intended for use in the *in vitro* diagnostic tests by the manufacturer;

- 4) Active medical device is any medical device whose effect depends on the source of energy or any source of energy that is not generated directly from the human body or gravity;
- 5) Implantable medical device is any medical device intended to be completely or partially surgically or physically incorporated into the human body or permanently incorporated into the body orifice and intended to remain in the body after a medical procedure;
- 6) Active implantable medical device is any active medical device intended to be completely or partially surgically or physically incorporated into the human body or permanently incorporated into the body orifice and intended to remain in the body after a medical procedure;
- 7) Custom-made device is any medical device that is specifically manufactured at the request of an appropriate healthcare professional who personally specifies the design characteristics of that medical device and is intended for a particular patient.

Custom-made device may be prescribed on a prescription or an order of a person authorised to do so in accordance with the law, or having appropriate professional qualifications.

Mass-produced medical device that needs to be adapted to the specific requirements of a healthcare professional or other professional user is not considered as a medical device manufactured according to the order;

- 8) Medical device intended for clinical investigation is any medical device intended for use by the appropriate healthcare professional in carrying out clinical trials in a health institution.

Another person shall be considered equivalent to the appropriate healthcare professional in the conduct of a clinical trial if authorised in accordance with the law, or who has appropriate professional qualifications for carrying out a clinical trial;

- 9) Single-use medical device is a medical device that is intended to be used only once for a single patient during a single procedure. A single-use medical device may be used

- repeatedly on the same patient or on the same patient over an extended period of time for a single procedure. A critical single-use medical device is a disposable medical device intended for use in surgical invasive procedures;
- 10) Medical device for self-testing means any *in vitro* diagnostic medical device intended to be used by non-professionals in the home environment;
 - 11) Performance assessment tool is any *in vitro* diagnostic medical device which the manufacturer has intended to be the subject of one or more tests for assessing performance in medical analysis laboratories or in any other appropriate environment outside its own premises;
 - 12) Calibrator and control material shall refer to every substance, material or product intended for the determination of measurement relationships or to check the characteristics of the medical device performance in relation to its purpose;
 - 13) Spare part of a medical device is a product that is an integral part of a medical device and is supplied and delivered exclusively for the needs of replacing the existing components of a medical device that is in compliance with the basic requirements. The spare part of a medical device is not considered a medical device;
 - 14) Category of medical devices is a set of medical devices that have a common area of intended use or common technology;
 - 15) Generic device group is a set of medical devices that have the same or similar use or common technology that allows them to be classified in a general manner without reflecting specific characteristics;
 - 16) Categorization of a medical device is a procedure for determining the category of medical device;
 - 17) Classification of a medical device is a procedure for determining the class of the risk of a medical device;
 - 18) Medical device whose manufacturing used animal tissues or products of animal origin is a medical device which must meet certain requirements regarding the risk of transmission of spongiform encephalopathy (TSE) to a patient or other person under normal conditions of use;
 - 19) Natural person is an entrepreneur, that is, a business-capable physical person who performs activity in order to generate income and which is registered as such, in accordance with the law regulating companies and the law regulating registration;
 - 20) Manufacturer of a medical device (hereinafter: the manufacturer) is a legal or natural person responsible for its design, manufacture, packaging and labelling before placing it on the market under its own name, whether or not these activities have been performed independently or on their behalf by another person;
 - 21) Authorised representative of a foreign medical device manufacturer (hereinafter: authorised representative of a manufacturer) is a legal or natural person with a head office in the Republic of Serbia who is solely authorised by the foreign manufacturer in writing to act on their behalf and to conduct the procedures prescribed by this Law and who is

- responsible for the safety and performance of a particular medical device in the same way as the manufacturer of that medical device;
- 22) Intended purpose is the use for which the medical device is intended in accordance with the information given by the manufacturer when labelling, in the instructions for use, or in the promotional material;
- 23) Performance of the medical device is the ability of the medical device to achieve the intended purpose of the manufacturer;
- 24) Compatibility of a medical device is the ability of a medical device, including the software, when used together with one or more other devices, in accordance with its purpose, to:
- (1) perform without losing or compromising the ability to perform as intended, or
 - (2) integrate, i.e. operate without the need for modification or adaption of any part of the combined device, or
 - (3) be used together without conflict, i.e. interference or adverse reaction;
- 25) Placing on the market is the first placement of a medical device with or without compensation in order to distribute or use on the market of the Republic of Serbia, regardless of whether it is new or completely renewed, except for a medical device intended for clinical trial;
- 26) Putting into service is the phase in which the medical device is available to the end user, ready for use on the market of the Republic of Serbia for the first time and for its intended purpose;
- 27) Free sale certificate is a document proving that a medical device can be marketed in the country of the manufacturer or on the market of a Member State of the European Economic Area (hereinafter: the EEA Member State);
- 28) Clinical data are all data on the safety, i.e. the performances of a medical device arising from the use of a medical device. Clinical data come from:
- (1) clinical trial i.e. clinical investigations of that medical device, or
 - (2) scientific literature on clinical trial i.e. clinical investigations or another investigation of a similar medical device for which equivalence with that medical device can be proved, or
 - (3) published or unpublished reports on other clinical experiences of that medical device or other similar device whose equivalence with that medical device can be proved;
- 29) Conformity assessment is any activity that determines whether the medical device, that is, the process of manufacturing a medical device, complies with the prescribed technical requirements, or systematic examination of the collected clinical evidence and procedures initiated by the manufacturer in accordance with the essential requirements (hereinafter: essential requirements), in order to establish that the medical device is safe and functioning in accordance with the intended purpose;

- 30) Conformity assessment body is a company, institution or other legal entity that conducts conformity assessment, or performs technical assessment tasks, including calibration, testing, certification and control. The conformity assessment body is a appointed body or an authorised body or a notified body;
- 31) Appointed body is the conformity assessment body, appointed by the Minister in charge of health (hereinafter: the Minister) to conduct conformity assessment for the needs of the manufacturer in accordance with this Law and the regulations adopted for its implementation;
- 32) Authorised body is the conformity assessment body, that is, the testing laboratory, the control body and the certification body, to whom the Minister has given the authority to carry out technical assessment tasks for the needs of the state administration body conducting the conformity assessment in accordance with this Law and the regulations adopted for its implementation;
- 33) Notified body is the conformity assessment body which is the competent authority of a particular EEA Member State or the state with which the European Commission has concluded a contract on the mutual recognition of conformity assessment procedures, reported to the European Commission for carrying out procedures for assessing the conformity of a medical device with the requirements of the European Union directives, which has its own identification number. A list of approved notified bodies for medical devices is located within the “NANDO” database of the European Commission;
- 34) Document of Conformity of the medical device is a declaration of conformity, a clinical trial report, a certificate, a control certificate or other document confirming the conformity of the medical device with the essential requirements (hereinafter: the Document of Conformity);
- 35) Declaration of Conformity is a document by which the manufacturer confirms that the medical device complies with the essential requirements (hereinafter: the Declaration of Conformity);
- 36) Certificate of Conformity of a medical device is an EC Certificate issued by a appointed body or certificate issued by a notified body certifying that the medical device or group of medical devices of a particular manufacturer complies with the essential requirements (hereinafter: Certificate of Conformity);
- 37) Technical assessment of a medical device is the testing, or control of a medical device carried out by an authorised conformity assessment body for the needs of the ministry responsible for health (hereinafter: the Ministry) in accordance with this Law and the regulations adopted for its implementation (hereinafter: technical assessment);
- 38) Marking of conformity of a medical device is a mark which the manufacturer places on a medical device and confirming that the medical device complies with the essential basic requirements. The marking of conformity may be the foreign marking of conformity (CE marking) or the Serbian marking of conformity of the medical device;

- 39) Serbian marking of conformity of a medical device is a mark certifying that the medical device placed on the market or in use is in compliance with the essential requirements in accordance with this Law and the regulations adopted for its implementation (hereinafter: Serbian conformity mark);
- 40) EUDAMED is a European database for medical devices that centralises registration data of manufacturers, or authorised representatives of manufacturers and medical devices placed on the market of the European Union, data on issued, amended, supplemented, as well as certificates that have ceased to be valid, which are withdrawn or rejected, data obtained in accordance with the procedure for the vigilance of medical devices and data on clinical trials;
- 41) CAMD is an association of competent authorities of the EU Member States for medical devices;
- 42) Distributor is a legal or natural person with headquarters or permanent residence in the Republic of Serbia, who is included in the supply chain and who supplies a medical device in the course of performing their activity, and is not a manufacturer, authorised representative of the manufacturer, wholesaler, importer;
- 43) Supplier is a manufacturer, an authorised representative of a manufacturer, wholesaler, importer or distributor;
- 44) Medical device vigilance is a set of activities that assure the collection, assessment, 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, provide information that reduces the likelihood of the incident being repeated or alleviating the consequences of the incident (hereinafter: vigilance);
- 45) Post-market surveillance monitoring are all activities carried out by the manufacturer or authorised representative of the manufacturer, establishing and maintaining a systematic procedure for proactively collecting and assessing the experience regarding a medical device that has been placed on the market, or in use, in order to identify any need to apply, without delay, all necessary corrective or preventive measures;
- 46) Market surveillance are activities carried out and measures undertaken by the Ministry and the Medicines and Medical Devices Agency of Serbia (hereinafter: the Agency) in order to check and ensure that the medical devices comply with the essential basic requirements, as well as do not endanger health, safety or any other aspect of the protection of the general interest;
- 47) Examination of the medical device is the activity of regular or extraordinary examination of the compliance of a medical device with the essential basic requirements for the safety and performance of the medical device during the lifetime of use;

- 48) Improper use is the act or omission by a person who handles a medical device or by the user, the consequence of which is the behaviour of a medical device that is beyond any risk control by the manufacturer;
- 49) Corrective action is the activity undertaken by the manufacturer, or the authorised representative of the manufacturer in the event of a potential or established non-conformity of a medical device or other unwanted situation. There may be more non-conformities. Corrective action is taken to prevent repetition, while preventive ones are taken to prevent such an event (Corrective and Preventive Action - CAPA);
- 50) Field Safety Corrective Action (FSCA) is a measure taken by the manufacturer or an authorised representative of the manufacturer to reduce the risk of death or serious deterioration in the health condition associated with the use of the medical device placed on the market. Such measures, regardless of whether they are related to direct or indirect damage, are reported and recorded through the Field Safety Notice;
- 51) Field Safety Notice (FSN) is a notice for customers, i.e. users sent from by the manufacturer, or an authorised representative of the manufacturer in relation to the Field Safety Corrective Action;
- 52) Damage is a physical injury or damage to the health of people, animals or damage to property or the environment;
- 53) Without delay is the method of urgent action, that is, the treatment whose postponement cannot be justified;
- 54) Vigilance Coordinator is a healthcare professional employed in a healthcare institution who carries out tasks related to organising and improving the implementation of good practice in collecting and reporting suspicions of incidents and communication about the risks of using medical devices in a health institution and who is the contact person of a health institution for the Agency for the vigilance and which directly cooperates with the Agency. The vigilance coordinator is appointed by a healthcare institution and reports to the Agency with contact information;
- 55) Incident is any malfunction or deterioration of the characteristics or performance of a medical device, as well as the inadequacy in the labelling or in the instruction for use which, directly or indirectly, led or could have led to the death of a patient, user or other person or serious deterioration their health;
- 56) Periodic Safety Report is a method of reporting agreed between the Agency and the manufacturer or the authorised representative of the manufacturer on the reporting of similar incidents of the same medical device or type of medical device in a unified manner when the cause is known or Field Safety Corrective Action is implemented;
- 57) Serious public health threat is any event that can lead to immediate danger of death, serious deterioration of health or serious illness requiring rapid corrective actions, and which includes:
- (1) events that are significant and unexpected in nature, so that they become alarming as a potential threat to public health, such as, for example, Human

Immunodeficiency Virus (HIV) or Creutzfeldt-Jakob Disease (CJD). This threat to public health may be identified by the Ministry, the Agency or the manufacturer, or the authorised representative of the manufacturer,

- (2) possibility of multiple deaths at short intervals;
- 58) Beneficiary is a health institution, a healthcare professional, a healthcare associate or a patient, i.e. a person using a medical device;
- 59) Person responsible for the vigilance and monitoring of the medical device on the market is a full-time employee at the manufacturer or an authorised representative of the manufacturer who performs vigilance tasks and has completed medical, dental, pharmaceutical, technological, electro-technical, mechanical, chemical or other appropriate faculty depending on the type of medical device, as well as additional education in the field of vigilance (hereinafter: person responsible for vigilance);
- 60) Person responsible for the documentation is a full-time employee at the manufacturer or an authorised representative of the manufacturer for affairs in the procedure of registration, modification, supplementation, renewal or removal of the registration of a medical device and who has completed medical, dental, pharmaceutical, technological, electro-technical, mechanical, chemical or law faculty;
- 61) Clinical trial of a medical device is any systemic investigation, examination or study conducted on one or more subjects that is carried out to assess the safety or performance of the medical device (hereinafter: clinical trial);
- 62) Adverse event in a clinical trial is any unpleasant medical occurrence, accidental illness or injury or an unfavourable clinical symptom (including an unfavourable laboratory finding) in a patient, user or other person, whether or not related to the medical device that is clinically studied. This definition includes events related to a medical device that is clinically studied or a medical device to compare with, as well as events related to the procedures involved. For users or other persons, this definition is limited to events relating to a medical device that is clinically studied;
- 63) Serious adverse event in a clinical trial is an unwanted event that led to or may lead to death or serious deterioration of the patient's health, resulting in life-threatening illness or injury or permanent damage to the body's structure or function, hospitalization of the patient, or the extension of existing hospital treatment, medical or surgical interventions to prevent illness or injury that is life-threatening or permanent damage to the structure or function, and which may lead to fetal distress, fetal death or congenital anomalies, or effect. Planned hospitalization for the pre-existing condition or procedure required by the Clinical Investigation Plan, without serious harm to health, is not considered a serious adverse event;
- 64) Adverse effect in a clinical trial is an adverse event in relation to the use of a medical device that is clinically studied. This definition includes adverse effects arising from insufficient or inadequate instructions for use, development, implantation, installation or operation or any malfunctioning of the medical device being clinically studied. This

definition includes any event resulting from an error in use or from the deliberate misuse of a medical device that is clinically studied;

- 65) Ethics Committee of Serbia is an independent expert body that takes care of the provision and implementation of healthcare at the level of the Republic of Serbia, on the principles of professional ethics, composed of prominent experts with significant results in work, as well as contributions in the field of healthcare, professional ethics of the healthcare workers and humanistic sciences in accordance with the law regulating healthcare, whose responsibility is to protect the rights, safety and well-being of subjects involved in a clinical trial, as well as to provide public protection of their rights;
- 66) Sponsor of the clinical trial is a legal or natural person, i.e. the person responsible for initiating, or obtaining approval for conducting a clinical trial, the implementation and financing of a clinical trial (hereinafter: the sponsor);
- 67) Lead investigator is a qualified person responsible for the conduct of a clinical trial at the clinical trial site. If a clinical trial is conducted by a team of individuals at the site of a clinical trial, the principal investigator is responsible for team management;
- 68) Investigator is an individual member of the team at the site of a clinical trial determined by and under the supervision of a lead investigator who performs key procedures in a clinical trial or makes important decisions in relation to a clinical trial (a “sub-investigator” or a “co-investigator”);
- 69) Informed consent of the subjects is a written statement, with the date and signature of the subject, about participation in a particular clinical trial, provided by a person capable of consenting or consent by a legal representative of a person unable to give consent, in accordance with the law, which was given voluntarily after full information about the nature, significance, consequences and health risks (hereinafter: informed consent);
- 70) Clinical Investigation Plan (CIP) is a document that sets out the basic principles, objectives, design, proposed analyzes, methodology, supervision, implementation and record of the clinical trial (hereinafter: the Protocol);
- 71) Clinical evaluation is the assessment and analysis of clinical data relating to a medical device in order to check the clinical safety and performance of the medical device;
- 72) Clinical Evaluation Report refers to the clinical evaluation documentation;
- 73) Clinical performance is the method of operation of a medical device or the patient's response to a medical device with respect to the purpose of that medical device when correctly applied to the appropriate patient;
- 74) Clinical safety is the absence of an unacceptable risk from a medical device when used in accordance with the manufacturer's instructions;
- 75) Device deficiency is any inadequacy of a medical device in relation to identity, quality, durability, reliability, safety or performance. Defects of a medical device include failures, malfunctions and inadequate labelling;

- 76) Multicentre clinical trial is a clinical trial conducted under a single Protocol at several clinical trial sites and which is carried out by more investigators, regardless of whether the clinical trials are in the same country or in different countries;
- 77) Post-marketing clinical trial is a clinical trial after completing the conformity assessment, or after labelling with the sign of compliance. Post-marketing clinical trial can be interventional and non-interventional;
- 78) Post Market Clinical Follow Up Plan (PMCF) are documented, proactive, organised methods and procedures established by the manufacturer for the collection of clinical data based on the use of a medical device labelled with a conformity mark in accordance with the technical documentation or based on the group of medical devices belonging to the same subcategory or general medical devices. The aim is to confirm the clinical safety and performance, as well as the acceptability of the identified risks during the expected lifecycle of the medical device and to detect the risks that may arise from fact-based evidence;
- 79) Manufacturing process is any process applied in the manufacturing of medical devices, from the procurement and acceptance of starting materials, manufacture, packaging into the inner packaging to labelling and the process of packaging in the outer packaging;
- 80) Fully refurbishing is the complete rebuilding of a medical device already placed on the market or into service or renewal of a medical device that has been used in order to comply with the essential requirements, with the determination of a new lifecycle of the renewed medical device;
- 81) Improvement is a process that is performed on a medical device that has been used to enable its safe reuse, including cleaning, disinfection, sterilization and similar procedures, as well as testing and restoring the technical and functional safety of the medical device;
- 82) Person responsible for the manufacture is a full-time employee with a manufacturer who is responsible for the preparation and implementation of the medical device manufacturing process;
- 83) Person responsible for quality is a full-time employee with a manufacturer who is responsible for the technical assessment of each batch of medical devices, or who is responsible for the quality of the medical device during the manufacturing process of the medical device, including the systematic documentation of all the starting materials and components, packaging material, intermediate products, manufacturing processes, as well as testing of the finished medical device;
- 84) Quality assurance is a follow-up process in which quality is introduced at all stages of manufacturing, including a system of documented monitoring of all starting materials and components and a single manufacturing process, or a technical assessment, which includes all controls in relation to the quality of the medical device;
- 85) Benefit-risk determination is the assessment of the positive effects of a medical device in relation to risks;

- 86) Batch is a defined quantity of starting materials (starting substances or packaging materials) or products made during one manufacturing process, i.e. manufacture or in a series of manufacturing processes, which should therefore be homogeneous. Batch included the total amount of a medical device that has been manufactured, i.e. made from the same initial quantity of starting materials during one manufacturing process, or the manufacture and one sterilization process, and in the case of continuous manufacture or manufacture, the total amount of a medical device that is produced or made in a certain period;
- 87) Good Clinical Practice Guidelines are a quality assurance standard for planning and conducting clinical trials to obtain valid clinical conclusions with the appropriate protection of participants in clinical trials;
- 88) Good Manufacturing Practice Guidelines are the quality assurance guidelines for the organisation, implementation and monitoring of the distribution of medical devices from the manufacturer to the end user;
- 89) Critical non-compliance of the medical device marketing with the Good Manufacturing Practice Guidelines is the non-compliance which led or may lead to the marketing of a medical device that could endanger the life or health of the public, ie. public health;
- 90) Specialized medical device store is a sales facility where retail sale of medical devices is carried out;
- 91) Inner package of a medical device is a package with which the medical device is in direct contact;
- 92) Outer package of a medical device is a package in which the inner packaging of the medical device is located;
- 93) Label is written, printed or graphical information on a medical device, on the packaging of each component of a medical device or on a package of the system or kit and contains information about the authorised representative of the manufacturer and the number of the decision on the registration of a medical device. A sticker with information on the number of decisions on the registration of a medical device in the Republic of Serbia can also be found on the instruction manual;
- 94) Falsified device is any medical device which is falsely presented in terms of identity, or origin, i.e. CE marking or documentation in connection with CE marking procedures. This definition does not apply to a medical device with inadvertent defects in quality (medical device quality defect) and does not undermine intellectual property rights;
- 95) Transit is the transport of a medical device through the territory of the Republic of Serbia, without changing the ownership of the consignment and without changing the destination and the user;
- 96) Unregistered entity is a supervised entity that performs an activity but is not registered in the appropriate register managed by the Business Registers Agency or another authority or organisation responsible for registering the founding of a legal entity and another

entity (hereinafter: the Basic Registry), when entry in this register is prescribed as a condition for performing activities;

- 97) Registration of a medical device is an administrative procedure for the entry of a medical device for which the assessment of conformity has been performed in the register of medical devices managed by the Agency;
- 98) Unique Device Identification (UDI) is a unique numerical or alphanumeric code referring to a medical device, in two following parts:
- (1) medical device identifier;
 - (2) manufacture identifier.

Unique Device Identification provides access to useful and relevant information regarding the medical device and makes the traceability of the medical device more effective, facilitates the withdrawal of the medical device from the Marketing, stops counterfeiting and improves patient safety. Unique Device Identification is not a substitute for or supplement to prescribed requirements for the labelling of a medical device.

II MEDICINE AND MEDICAL DEVICES AGENCY OF SERBIA

1. The Agency's operations in the field of medical devices

Article 3

The Agency shall be responsible for the following:

- 1) Performs registration of a medical device, amendments, renewal of registration, as well as removal of a medical device from the Register of Medical Devices;
- 2) Keeps the Register of Manufacturers, or authorised representatives of the manufacturers (hereinafter: the Register of Manufacturers), makes amendments and removals from the Register of Manufacturers;
- 3) Approves the implementation, modifications and amendments of the approval for the conduction of the clinical trial, confirms the report of the clinical trial and approves the import of clinical trial products in accordance with this Law, and also controls the conduction of the clinical trial;
- 4) Assess the compliance of the medical device with the requirements of the monograph of the national pharmacopoeia, as well as the applicable European pharmacopoeia or international pharmacopoeia;
- 5) Performs recognition of foreign documents and markings of conformity;
- 6) Performs a technical assessment of the medical device on the market with the requirements of the national pharmacopoeia monograph, as well as the applicable European pharmacopoeia or international pharmacopoeia, as well as with the requirements of the manufacturer's standards and methods;

- 7) Performs surveillance of the medical device on the market, conducts a vigilance and participates in the planning and implementation of systematic control of medical devices and taking random samples from the market;
- 8) Approves the import of a medical device for the treatment of a particular patient or group of patients, the import of a medical device as a donation or humanitarian aid, or a grant program in the European Union, a medical device for scientific research, as well as in case of an emergency situation in accordance with the law;
- 9) Controls the promotional material for the advertising of a medical device, on the proposal of the Ministry;
- 10) Collects and processes data on Marketing and consumption of medical devices;
- 11) Determines the status of the product, i.e. determines whether a particular product is a medical device;
- 12) Gives opinion on the classification and categorization of the medical device, at the request of the Ministry;
- 13) Cooperates with international information networks on medical devices and with agencies responsible for medical devices and their associations;
- 14) Grants approval for the import and export of samples of cells or tissues for the clinical trial procedure;
- 15) Issues a Free sale certificate for a medical device that has been placed on the market or in use;
- 16) Informs the general and professional public, as well as performs continuous medical education, in accordance with the law, and prepares and publishes professional publications within the competence of the Agency;
- 17) Provides professional advice at the request of legal or natural persons in connection with:
 - (1) the translation of the instructions for use and the marking of a medical device,
 - (2) classification of a medical device in the class and category of medical devices;
- 18) Performs other duties, in accordance with the law.

The tasks referred to in paragraph 1 items 1), 3), 4), 5), 6), 8), 11) and 14) of this Article, the Agency performs as the entrusted tasks.

The operations referred to in paragraph 1 of this Article may be performed in electronic form in accordance with the law governing electronic commerce.

In the performance of the entrusted tasks referred to in paragraph 2 of this Article, the law governing the general administrative procedure shall be applied, unless otherwise provided by this Law.

The Minister shall prescribe the criteria and manner of determining the status of products referred to in paragraph 1, item 11 of this Article.

2. Regulations applicable to the work of the Agency

Article 4

In addition to the provisions of this law, the law regulating public agencies and the law regulating medicinal products (scope of work of the Agency, resources for operation, bodies and general acts of the Agency) shall apply to the work of the Agency.

The law governing the general administrative procedure and the law governing civil servants shall apply to the exemption of employees in the Agency from participation in proceedings before the Agency.

3. Advisory bodies of the Agency

Article 5

The Agency, with the prior approval of the Minister, shall establish advisory bodies (hereinafter: the commissions) for the purpose of giving opinions in accordance with this Law and the regulations adopted for its implementation.

The members of the commission referred to in paragraph 1 of this Article may be permanent members, as well as members of the commissions upon invitation for a certain type of medical device.

Persons from the ranks of prominent experts in the field of medical devices shall be selected as members of the commission referred to in paragraph 1 of this Article.

The members of the commission referred to in paragraph 1 of this Article shall be excluded from participation in the process of issuing commission's opinion in which they, as well as their relatives in the direct line, regardless of the degree of kinship, collateral relatives concluding with a second degree of kinship, adoptive parents or adoptive child, spouses and relatives by in-laws concluding with the first degree of kinship, directly or through the third legal or natural person or individuals, participate as shareholders, stakeholders, employees, participate in the management bodies or perform jobs under the contract, perform consulting, representation, presentation and the like in a legal or natural person who performs the activity of manufacture, trade and testing of the medical devices, as well as at the manufacturer or authorised representative of the manufacturer, i.e. perform this activity as natural persons, about which they shall sign a statement in order to prevent conflicts of private and public interest.

The members of the commission referred to in paragraph 1 of this Article shall be appointed for four years and may be reappointed.

The Agency, with the prior approval of the Minister, shall dismiss a member of the commission who acts contrary to paragraph 4 of this Article, as well as if they do not perform tasks within the competence of the commission, or if they perform them irresponsibly.

The expenses of the commissions referred to in paragraph 1 of this Article shall be provided from the resources of the Agency.

On its official website, the Agency shall publish decisions on the appointment and dismissal of the members of the commissions referred to in paragraph 1 of this Article, without delay, and no later than within three days from the day of issuing the decision.

4. List of experts

Article 6

The Agency, with the prior consent of the Minister, may determine the list of medical experts for the purpose of giving opinions in accordance with this Law and the regulations adopted for its implementation.

Experts from the list referred to in paragraph 1 of this Article shall be selected from the rank of prominent experts in the field of medical devices and must fulfil the requirements of Article 5, paragraph 4 of this Law.

Experts from the list referred to in paragraph 1 of this Article shall be appointed for four years and may be reappointed.

The Agency, with the prior approval of the Minister, shall dismiss an expert from the list of experts referred to in paragraph 1 of this Article who acts contrary to paragraph 2 of this Article, as well as if they do not perform tasks within their competence or if they perform them irresponsibly.

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

The Agency shall publish on its official website a list of experts referred to in paragraph 1 of this Article, which it is obliged to update without delay, and at the latest three days from the date of the change in the list.

5. Tariffs for the activities of the Agency

Article 7

The Agency issues a tariff for the provision of the following services:

- 1) Registration of a medical device, amendments and renewal of registration, as well as removal from the Register of Medical Devices;
- 2) Issuance of an approval, amendment to the approval of a clinical trial, as well as a certificate of acceptance of the application for conducting a clinical trial and approval of the import of a clinical trial product in accordance with this Law;

- 3) Approving the import of a medical device for the treatment of a particular patient or group of patients, as well as a medical device for scientific research;
- 4) Vigilance;
- 5) Approval of the import and export of samples of cells or tissues for the clinical trial procedure;
- 6) Opinion on the status of the product, classification and categorization of the medical device at the request of the manufacturer or the authorised representative of the manufacturer;
- 7) Assessing the compliance of the medical device with the requirements of the national pharmacopoeia monograph, as well as the applicable European pharmacopoeias or international pharmacopoeias;
- 8) Recognition of foreign documents and markings of conformity, at the request of the manufacturer or the authorised representative of the manufacturer;
- 9) Technical assessment of the medical device on the market with the requirements of the national pharmacopoeia monograph, as well as the applicable European pharmacopoeias or international pharmacopoeias, as well as the requirements of the manufacturer's standards and methods;
- 10) Informing the professional public, continuous medical education and preparing and issuing professional publications within the Agency's competence;
- 11) Expert advice at the request of legal or natural persons in relation to:
 - (1) the translation of the instructions for use and labelling of a medical device,
 - (2) the classification of products into a group of medical devices,
 - (3) the classification of a medical device in the appropriate risk class;
- 12) Issuance of the Free Sale Certificate for a medical device that has been placed on the market or in use, for export purposes.

Fees for the provision of services under the tariff referred to in paragraph 1 items 1) to 9), 11) and 12) of this Article shall be paid by the applicant.

Fees for the provision of services referred to in paragraph 1, item 10) of this Article shall be paid by the user of the services.

Notwithstanding paragraph 2 of this Article, the Agency shall not charge the tariffs for the activities referred to in paragraph 1 of this Article relating to medical devices from donations and humanitarian aid, i.e. the program of donation in the European Union, in the event of an emergency situation, as well as for performing activities at the request of the Ministry.

The amount and method of payment of tariffs and fees referred to in paragraph 1 of this Article shall be determined by the Management Board of the Agency.

The Government shall give its approval to the Agency's act determining the tariffs for services referred to in paragraph 2 of this Article, which, after receiving the approval of the Government, shall be published in the "Official Gazette of the Republic of Serbia".

6. Supervision of the work of the Agency

Article 8

Supervision over the work of the Agency in the performance of entrusted tasks of state administration, as well as supervision over the professional work of the Agency, is carried out by the Ministry.

7. Appeal procedure in the administrative procedure

Article 9

An appeal may be filed to the Ministry on the decisions of the Agency referred to in Article 3, paragraph 1, items 1), 3), 4), 5), 6), 8), 11) and 14) of this Law.

The decision of the Ministry is final in the administrative procedure and an administrative dispute can be initiated against it.

III EMERGENCY SITUATIONS

Article 10

For prevention, or to prevent the occurrence of serious consequences for public health in the event of an epidemic, as well as in other emergency situations, the Government may, at the proposal of the Minister, prescribe a different way and conditions for placing medical devices on the market and their registration, for clinical trials, manufacture, technical evaluation of medical devices, labelling, vigilance, advertising, as well as the use of medical devices, from the conditions prescribed by this Law and the regulations adopted for its implementation.

IV INFORMATION CONFIDENTIALITY

Article 11

The employees of the Agency, the members of the bodies and advisory bodies of the Agency, experts from the list of experts, as well as employees of the Ministry, are obliged to keep as a business secret all the information from the documentation that is enclosed with the application for registration of a medical device, as well as in other procedures that are conducted before the Agency, or in the Ministry, especially if:

- 1) The information is secretive, or if, as a whole or in a precise form and set of its components, they are not generally known or are not easily accessible to persons who are normally engaged in that type of information;

- 2) The data have a commercial value due to its secrecy, during the period of such secrecy;
- 3) The manufacturer or authorised representative of the manufacturer, in given circumstances, takes reasonable steps to keep the data secret.

The persons referred to in paragraph 1 of this Article as a business secret also preserve the data from the documentation for registration of a medical device, amendments or renewal of the registration, relating to undisclosed testing of medical devices.

In order to combat unfair competition, employees and persons referred to in paragraph 1 of this Article shall not disclose information from the documentation submitted in the procedure for registration of a medical device, as well as in other procedures that are conducted before the Agency or the Ministry, with the consent of the manufacturer, the authorised representative of the manufacturer or the applicant for other procedures being conducted before the Agency or the Ministry, as well as in addition to the data available to the expert and general public for the purpose of providing information on medical device which are necessary for the use or operation, as well as the protection of public health. The right to access this information is exercised in accordance with the law regulating free access to information of public importance.

In case of violation of obligations from paragraphs 1, 2 and 3 of this Article, regulations relating to the protection of business secrets shall apply.

The protection of data referred to in paragraph 2 of this Article shall be subject to the regulations on the protection of intellectual property rights.

V ESSENTIAL REQUIREMENTS FOR THE MEDICAL DEVICE

1. Placing a medical device on the market and into service - essential requirements

Article 12

A medical device may be placed on the market, or in use only if it is in compliance with the essential requirements (if its compliance is assessed by the prescribed procedure, if it is labelled in accordance with this Law and the regulations adopted for its implementation, if an appropriate document was issued on conformity and other documentation prescribed by this Law and the regulations adopted for its implementation) and when properly procured and installed, maintained and used in accordance with its purpose.

The medical device that is the source of ionizing radiation, in accordance with the law, must also fulfil the conditions laid down by the regulations governing the protection against ionizing radiation.

When there is a significant risk, medical devices that are also machines in accordance with the law must fulfil the prescribed essential health and safety requirements to the extent that these

requirements are more specific than the essential requirements prescribed by this Law and the regulations adopted for its implementation.

If the purpose of the medical device is to be used as personal protective equipment, the medical device must also meet the relevant essential requirements for personal protective equipment.

The Minister shall prescribe the essential requirements for medical devices referred to in paragraph 1 of this Article.

2. Assumption of conformity

Article 13

It is assumed that the medical device meets the essential requirements prescribed by this Law and the regulations adopted for its implementation if it is manufactured in accordance with Serbian standards in the field of medical devices to which the relevant harmonized standards of the European Union have been taken.

The list of standards referred to in paragraph 1 of this Article shall be compiled and published in accordance with the law regulating technical requirements for products and conformity assessment, and regulations adopted for its implementation.

The Minister shall publish the consolidated list of Serbian standards referred to in paragraph 1 of this Article.

A list of the standards referred to in paragraph 2 of this Article shall be published in the “Official Gazette of the Republic of Serbia” on the form whose contents are prescribed by the Minister in charge of standardization matters.

The Serbian standards referred to in paragraph 1 of this Article also include the national pharmacopoeia monographs, as well as the applicable European pharmacopoeias or international pharmacopoeias, especially in relation to the surgical sutures, as well as the interaction between drugs and materials used as an integral part of the medical device containing such medical devices.

3. Applicable application

Article 14

The provisions of the law regulating technical requirements for products and conformity assessment and the regulations adopted for its implementation shall apply accordingly to:

- 1) Appointment or authorisation of the conformity assessment body;
- 2) Registration of the appointed or authorised body for the assessment of conformity;

- 3) Method of carrying out the conformity assessment, the content of the compliance document, and the shape, appearance and content of the marking of conformity;
- 4) Reporting technical regulations.

4. Assessment of conformity

Article 15

Assessment of conformity in accordance with the essential requirements, prior to placing on the market, is carried out by the manufacturer or conformity assessment body, and the technical assessment is carried out by the conformity assessment body by controlling the final product according to the technical specification, in accordance with this Law and the regulations adopted for its implementation.

The conformity assessment procedure is a procedure that determines and assesses whether the medical device or its manufacture meets the essential requirements.

The procedure for assessing compliance with the essential requirements is carried out depending on the class of the risk of a medical device.

If the conformity assessment procedure requires the inclusion of the conformity assessment body, the manufacturer is required to select the body to assess the conformity of the relevant scope of jurisdiction with headquarters in the EEA Member State or the country with which the European Commission has concluded a contract on the mutual recognition of conformity assessment procedures - the notified body or with the seat in the Republic of Serbia - an appointed or authorised body.

The conformity assessment of medical devices of Class I (other than the Is and Im class) and the class of other *in vitro* diagnostic medical devices are not performed by the conformity assessment body, i.e. the conformity assessment is performed by the manufacturer.

The conformity assessment of the products referred to in Article 1, paragraph 9 of this Law shall be carried out in accordance with common specifications ("CS") issued by the European Commission for specific product groups not intended for medical purposes. Common specifications represent a set of technical, that is, clinical requirements, which are not standard, and which provide a way of compliance with legal obligations applicable to medical devices, processes or systems.

The Minister shall publish the list of products referred to in paragraph 6 of this Article.

The manufacturer or the authorised representative of the manufacturer shall keep the declaration of conformity, the technical documentation prescribed by this Law and the regulations adopted for its implementation, as well as the decisions, reports and certificates issued by the conformity assessment bodies and shall be made available to them by the inspection of the Ministry 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.

Assessment of compliance with the national pharmacopoeia monograph, as well as the valid European pharmacopoeias or international pharmacopoeias, is performed by the Agency.

The technical evaluation is carried out by the Agency and the authorised body, which must be accredited for technical evaluation tasks from the accreditation body of the Republic of Serbia, in accordance with the law. The Accreditation Act shall be deemed to be evidence that the authorised body is competent for a technical evaluation in relation to activities in the scope of accreditation which is an integral part of the Accreditation Act. The Accreditation Body of the Republic of Serbia may request the opinion of the Ministry regarding the proposed scope of accreditation. The Ministry may participate in the accreditation process of the conformity assessment body as an observer, upon the proposal of the accreditation body of the Republic of Serbia, with the consent of the applicant.

The decision on the authorisation of the conformity assessment body shall be made by the Minister in accordance with the law regulating the general administrative procedure. The accreditation body of the Republic of Serbia, in the capacity of an observer, may participate in the procedure of authorisation of the conformity assessment body, upon the proposal of the Ministry, with the consent of the applicant.

If the Ministry determines that the authorised body has ceased to fulfil the condition referred to in paragraph 10 of this Article or does not fulfil its obligations in accordance with the law, the Minister shall issue a decision on the annulment of the decision referred to in paragraph 11 of this Article in accordance with the law regulating the general administrative procedure .

Before issuing the decision referred to in paragraph 12 of this Article, the Minister may, taking into account the type of defect in respect of the fulfilment of the essential requirements or the fulfilment of obligations, in written form, warn the authorised body and set a deadline for the elimination of deficiencies which cannot be longer than 60 days .

The decision referred to in paragraph 12 of this Article is final in the administrative procedure and an administrative dispute can be initiated against it.

If the Minister adopts the decision referred to in paragraph 12 of this Article or if the authorised body ceases to operate, the Minister may order it to carry out, within a certain period of time, the transfer of documentation related to the assessment of conformity to another authorised body at the choice of the manufacturer, or make the availability of such documentation available to the competent authorities .

The electronic records of authorised bodies in the field of medical devices are established and maintained by the Serbian Chamber of Commerce, as an entrusted job.

Supervision of the work of an authorised body is carried out by the Ministry.

5. Foreign documents and marks of conformity

Article 16

Foreign certificates of conformity are: certificate, test report, declaration of conformity, certificate of control or other document confirming the conformity of a medical device with the essential requirements of the European Union regulations issued by the notified body or accredited laboratory.

The foreign mark of conformity is the CE marking that is placed on a medical device in accordance with the essential requirements of European Union regulations (hereinafter: CE marking).

Recognition of foreign documents and CE marking from paragraphs 1 and 2 of this Article is performed by the Agency in the procedure of registration of a medical device.

Notwithstanding paragraph 3 of this Article, the Agency may recognize a foreign document or CE marking at the request of the manufacturer or the authorised representative of the manufacturer.

The Minister shall prescribe more closely the conditions and the manner of recognition of foreign documents and the CE marking from paragraphs 1 and 2 of this Article.

6. Freedom of movement, medical devices for special purposes

Article 17

A medical device may be placed on the market, or in use, only if it is labelled with a CE marking or a Serbian conformity mark in accordance with the law (hereinafter: the mark of conformity), which proves that conformity assessment has been performed.

Prior to placing the medical device on the market, or in use, the assessment of conformity may be carried out, or in which shall participate:

- 1) Manufacturer;
- 2) Notified, or appointed body for the assessment of conformity, at the choice of the manufacturer or the authorised representative of the manufacturer.

The Minister shall prescribe the method of assessing conformity and the type of certificate of conformity that the entity referred to in paragraph 2 of this Article shall be obliged to provide or issue for a medical device prior to its placing on the market or use.

Article 18

A medical device that is considered to be in compliance with the essential requirements, except a custom made device manufactured for specific patient or intended for a clinical trial, must bear a mark of conformity when placed on the market.

The mark of conformity must be visible, legible and indelible on the medical device itself or on a package which provides sterility, when feasible and applicable, as well as the instructions for use. If applicable, the mark of conformity must also be on the sales or commercial packaging.

It is forbidden to point out labels or inscriptions that could mislead third persons in relation to the meaning or graphic appearance of the mark of conformity. The other mark may be placed on a medical device, packing or instruction for use only if this does not impair the visibility and legibility of the mark of conformity.

Article 19

A medical device intended for clinical trials and a custom made device on the market must be accompanied by a statement from the manufacturer or an authorised representative of the manufacturer on the special purpose of the medical device in accordance with this Law and the regulations adopted for its implementation.

A medical device intended for display at business fairs, exhibitions, presentations, etc. does not have to fulfil the conditions prescribed by this Law and the regulations adopted for its implementation, provided that a warning is indicated in a visible place that this medical device is not in compliance with the essential requirements and that its trade or use is forbidden for any purpose until it is in conformity with the essential requirements.

The information necessary for the safe use of a medical device for the intended purpose, which is accompany medical device on the market or use in the Republic of Serbia, must be in Serbian and written in an understandable manner that takes into account the knowledge of the potential user, except the packaging of the medical device for professional use in accordance with this Law.

When other regulations requiring the placing of the mark of conformity are applied to the medical device, this mark is evidence that this 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 mark of conformity shall indicate that this medical device meets the provisions of only those regulations applied by the manufacturer. In this case, the manufacturer is obliged to document the detailed data contained in these regulations in the information or instructions for use required by these regulations and accompanying the medical device.

7. Incorrectly placed mark of conformity

Article 20

If the Ministry determines that the mark of conformity has been placed unjustifiably or not placed at all, the manufacturer or authorised representative of the manufacturer or importer of a medical device that is not registered under Article 79 of this Law shall take appropriate corrective measures without delay.

If the manufacturer or the authorised representative of the manufacturer or importer fail to take appropriate corrective measures in the case referred to in paragraph 1 of this Article, the Ministry shall limit or prohibit the placing on the market of that medical device, or take measures for its withdrawal in accordance with Article 21 of this law.

Provisions of paragraphs 1 and 2 of this Article shall also apply if the mark of conformity is placed in accordance with this Law on products to which this law does not apply or which are not medical devices.

8. Protective clause

Article 21

If it is established that a medical device that complies with the essential requirements, when properly installed, maintained and used in accordance with its purpose, could endanger the health or safety of the patient, user or other person, the Ministry, upon report or official duty, it requires the following measures:

- 1) Withdrawal from the market;
- 2) Ban or restriction of placing on the market, or for use.

The Ministry shall, without delay, notify the Agency and the appointed body of the measures taken from paragraph 1 of this Article, stating the reasons, and in particular:

- 1) That the medical device does not meet the essential requirements of Articles 12 and 13 of this Law;
- 2) Due to incorrect application of the provisions of Article 13 of this Law;
- 3) Due to the lack of technical standards.

If it is established that the medical device does not meet the essential requirements and is bearing a mark of conformity, the Ministry shall take appropriate measures and inform the Agency and, as appropriate, the conformity assessment body.

9. Medical device manufactured in a healthcare institution for use in that healthcare institution

Article 22

The provisions of this Law, in addition to the provisions governing the general requirements for the safety and performance of a medical device, shall not apply to a medical device that is produced in a healthcare institution for use only in that healthcare institution if:

- 1) A medical device is not, with or without compensation, given to another legal or natural person;
- 2) The manufacture and use of a 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 group of patients cannot be fulfilled or cannot be met at the appropriate level of performance by an equivalent medical device available on the market;
- 4) The healthcare institution once a year provides information on the use of medical devices to the Ministry, with an explanation of their manufacture, modification and use;
- 5) The healthcare institution shall prepare and make publicly available the statement containing: the name and address of the healthcare institution that manufactures the medical device, the details necessary for the identification of the medical device, the guarantee that the medical device meets the general requirements for safety and performance in accordance with this Law and the regulations adopted for its implementation, or, if necessary, information on which requirements have not been fulfilled, with explanation;
- 6) The healthcare institution develops documentation of the space, equipment, personnel and the manufacture process, design and performance of the medical device, including the purpose, which is sufficiently detailed to enable the Ministry to determine that the general requirements for safety and performance are met, in accordance with this Law and the regulations adopted for its implementation;
- 7) The healthcare institution shall take all necessary measures to ensure that the medical device is made in accordance with the documentation referred to in item 6) of this paragraph;
- 8) The healthcare institution, on the basis of experience acquired through clinical use of a medical device, undertakes all necessary corrective measures.

A permit for the manufacture of a medical device referred to in paragraph 1 of this Article shall be issued to the health institution by the Ministry.

A medical device made in a healthcare institution may be put into service in that healthcare institution and may not be placed on the market of the Republic of Serbia.

The Ministry may prohibit or restrict the development or use of a medical device referred to in paragraph 1 of this Article if the healthcare institution fails to fulfil, or ceases to fulfil the requirements prescribed by this Law and the regulations adopted for its implementation.

The Minister shall prescribe the conditions and manner of issuing the manufacturing permit as well as the general requirements for the safety and performance of the medical device referred to in paragraph 1 of this Article.

VI TYPES OF MEDICAL DEVICES

Article 23

Types of medical devices are:

- 1) General medical devices;
- 2) *In vitro* diagnostic medical devices;
- 3) Active implantable medical devices.

1. Classification of general medical devices

Article 24

The general medical devices according to the degree of risk for the users are divided into:

- 1) Class I - medical devices with low degree of risk for the user;
- 2) Class IIa - low to medium degree of risk for the user;
- 3) Class IIb – medium to high degree of risk for the user;
- 4) Class III - medical devices with a high degree of risk for the user.

The classification of medical devices shall be carried out by the notified i.e. appointed body, in accordance with the essential requirements, except for medical devices of Class I and other *in vitro* diagnostic medical devices, whose classification is carried out by the manufacturer.

In the event of a dispute between the manufacturer and the appointed body in relation to determining the class of a medical device, the decision shall be made by the Ministry on the basis of the previously obtained opinion of the Agency.

The Minister shall prescribe the conditions and rules for the classification of general medical devices and *in vitro* diagnostic medical devices.

2. Systems and kits of medical devices and the sterilization process

Article 25

Any legal or natural person who assembles medical devices with a mark of conformity, and in accordance with their purpose and within the limits of use provided by the manufacturer, shall place them on the market as a system or a kit, if they make the following statement:

- 1) That they verified the mutual compatibility of medical devices that are an integral part of the system or a kit and performed the assembly procedure in accordance with the manufacturer's instructions;
- 2) That they packed a system or a kit and provided the user with instructions for use including appropriate instructions for use by the manufacturer;
- 3) That appropriate methods of internal control of the medical device manufacture shall apply on the activities from items 1) and 2) of this paragraph.

If the requirements referred to in paragraph 1 of this Article are not fulfilled, as well as when the system or kit contain products which do not carry a conformity mark or when the combination of the selected products is not compatible with their intended purpose, the system or *kit* shall be considered as a medical device subject to the conformity assessment procedure.

Any legal or natural person, who for the purposes of placing on the market, sterilizes the systems or kits referred to in paragraph 1 of this Article or other medical devices bearing the mark of conformity and which the manufacturers have determined to be sterilized prior to use, shall be obliged to carry out the sterilization process in accordance with the appropriate quality system for the sterilization procedure prescribed by this Law and the regulations adopted for its implementation, of their own choice. The application of these procedures is limited to achieving sterility until the sterile package is opened or damaged. This person shall prepare a statement stating that the sterilization was done in accordance with the manufacturer's instructions.

Systems and kits from paragraphs 1 and 3 of this Article shall not be labelled with a mark of conformity. Systems and kits are followed by an instruction manual that, if necessary, includes information from the manufacturer on medical devices that constitute the system or kit.

The manufacturer is obliged to keep the statements from paragraphs 1 and 3 of this Article for five years and deliver them at the request of the Ministry or an appointed body.

VII APPOINTED BODY

Article 26

The conformity assessment body with the seat in the Republic of Serbia must be accredited by the accreditation body of the Republic of Serbia in accordance with the law and appointed by the Minister for carrying out certain conformity assessment activities.

The conformity assessment body must fulfil the essential requirements in relation to activities within the scope of accreditation which is an integral part of the Accreditation Act referred to in paragraph 1 of this Article, and in particular with regard to:

- 1) Professional qualifications of employees and other engaged persons;

- 2) Space and equipment;
- 3) Independence and impartiality in relation to persons associated with a medical device subject to the assessment of conformity;
- 4) Handling complaints about their work and decisions;
- 5) Keeping business secrets;
- 6) Liability insurance for damages.

The Accreditation Act referred to in paragraph 1 of this Article shall be deemed to be evidence that the conformity assessment body is competent for assessing compliance with the essential requirements in relation to activities within the scope of accreditation which is an integral part of the Accreditation Act or in relation to the procedure for assessing the compliance of the medical device of specified type and class. The Accreditation Body of the Republic of Serbia may request the opinion of the Ministry regarding the proposed scope of accreditation. The Ministry may participate in the accreditation process of the conformity assessment body as an observer, upon the proposal of the Accreditation Body of the Republic of Serbia with the consent of the applicant.

The decision on the appointment of a conformity assessment body shall be made by the Minister in accordance with the law governing the general administrative procedure. The accreditation body of the Republic of Serbia in the capacity of an observer, upon the proposal of the Ministry, with the consent of the applicant, may participate in the procedure for appointing a body for the assessment of conformity.

If the appointed body ceases to fulfil the conditions from paragraph 1 and 2 of this Article or does not fulfil its obligations in accordance with the law, the Minister shall issue a decision on termination of the decision referred to in paragraph 4 of this Article in accordance with the law regulating the general administrative procedure.

Prior to the decision referred to in paragraph 5 of this Article, the Minister may, taking into account the type of deficiencies in respect of the fulfilment of essential requirements or the fulfilment of obligations, in written form, warn the appointed body and set a deadline for the elimination of deficiencies which cannot be longer than 60 days .

The decision referred to in paragraph 5 of this Article is final in the administrative procedure and an administrative dispute can be initiated against it.

If the Minister passes the decision referred to in paragraph 5 of this Article or if the appointed body ceases to operate, the Minister may order it to carry out, within a specified period, the transfer of documentation related to the assessment of conformity to another appointed body at the choice of the manufacturer, or to enable the availability of such documentation to the competent organs.

The register of the appointed bodies shall be kept by the ministry responsible for economic affairs in accordance with the law.

The electronic records of the appointed bodies for assessing compliance in the field of medical devices are established and maintained by the Serbian Chamber of Commerce as an entrusted job.

Article 27

The appointed body and the manufacturer or the authorised representative of the manufacturer shall determine by mutual agreement the deadlines for carrying out the conformity assessment procedure and the verification of conformity prescribed by this Law and the regulations adopted for its implementation, which relate to examination of type, verification, quality assurance of manufacture and quality assurance of medical device.

In the conformity assessment procedure, the appointed body, that is, the manufacturer or the authorised representative of the manufacturer is obliged to take into account the results of all assessment and verification operations which, if necessary, have been carried out in accordance with this Law and the regulations adopted for its implementation at the phase of manufacture of intermediate products.

The appointed body is obliged to inform the Ministry and the Agency about all issued, amended, suspended and withdrawn certificates, as well as certificates for which the issuance was refused.

The appointed body shall also inform other conformity assessment bodies appointed in accordance with this Law on certificates that have been suspended, withdrawn or whose issuance has been refused, and, upon request, on certificates issued to the manufacturer or to the authorised representative of the manufacturer.

The appointed body shall, upon request from paragraphs 3 and 4 of this Article, also provide other additional relevant information.

When the appointed body establishes that the essential requirements have not been met or that the manufacturer no longer fulfils them or that the certificate should not have been issued, the appointed body shall, in respect of the type and scope of nonconformity, be obliged to suspend, withdraw or limit the issue of the certificate, unless the manufacturer shall, by implementing appropriate corrective measures, ensure compliance with essential requirements. In case of suspension, withdrawal or restriction of the certificate, the appointed body informs the Ministry and the Agency.

The appointed body shall, upon request of the Ministry, provide relevant information and documentation, including the financial documentation necessary for the Ministry to verify compliance with the essential requirements with respect to the labelling with the Serbian conformity marking.

The appointed body may, where justified, require the manufacturer or authorised representative of the manufacturer to provide all the information and data necessary for the establishment and maintenance of a certified conformity in relation to the chosen conformity assessment procedure.

If the assessment of conformity has been carried out by the notified body, the obligations from paragraphs 3 and 4 of this Article shall apply to the manufacturer or the authorised representative of the manufacturer.

Article 28

Supervision over the work of the appointed body shall be carried out by the Ministry.

VIII CLINICAL TRIAL

1. Standards for carrying out clinical trials

Article 29

Clinical trial is conducted in accordance with the guidelines of the good clinical practice in the clinical trial, i.e. the standard for clinical trials of medical devices on humans by the World Organisation for Standardization (ISO 14155).

Clinical trial shall be conducted on the basis of the approval of implementation or confirmation of the application for a clinical trial issued by the Agency and the positive opinion of the Ethics Committee of Serbia in accordance with this Law and the regulations adopted for its implementation.

The request for approval of the implementation of the clinical trial and the request for the opinion of the Ethics Committee of Serbia referred to in paragraph 2 of this Article shall be submitted through the Agency at the same time in accordance with this Law and the regulations adopted for its implementation.

The safety and performance of an *in vitro* diagnostic medical device are assessed on the basis of performance assessment studies.

The Minister shall prescribe the contents of the request referred to in paragraph 3 of this Article, i.e. the documentation for the approval of the clinical trial and the opinion of the Ethics Committee of Serbia, that is, the application of the clinical trial to the Agency, the conditions and manner of implementation, as well as the amendments to the clinical trial.

The essential requirements for the clinical evaluation of a medical device shall be prescribed by the Minister.

2. Protection of subjects in the conduct of clinical trials

Article 30

The protection of the rights, safety and interests of the subjects in the conduct of clinical trials must be a priority in relation to the contribution to science and the society as a whole.

Clinical trial must be planned and carried out to minimize as much as possible the pain, discomfort, fear and any other predictable risks for the health of the subjects.

The subject can at any time withdraw an informed consent, or withdraw from participating in a clinical trial.

3. Conducting clinical trials on vulnerable groups

Article 31

Clinical trial on vulnerable groups may be carried out only if it is in their interest and if their rights, safety, dignity and well-being are guaranteed, under the conditions prescribed by this Law and the regulations adopted for its implementation, and in particular to:

- 1) Persons who have not turned 18 years of age (hereinafter: juveniles);
- 2) Persons partially or completely deprived or working capacity (hereinafter: persons deprived of working ability);
- 3) Pregnant women and nursing mothers;
- 4) Persons who find themselves in a state of emergency or who require urgent medical assistance;
- 5) Persons placed in social welfare institutions;
- 6) Persons on mandatory military service;
- 7) Persons deprived of their freedom;
- 8) Persons who, according to the court decision, cannot participate in a clinical trial;
- 9) Persons who, by coercion or other mode of action, may be influenced to give an informed consent.

4. General requirements for carrying out clinical trials

Article 32

Clinical trial may be conducted if:

- 1) The benefit of the use of a medical device that is clinically studied is greater than its potential risk to the life and health of the subjects;
- 2) The Agency approved the conduct of a clinical trial;
- 3) The Ethics Committee of Serbia gave a positive opinion on the clinical trial, with particular reference to the clinical state of the subjects, ethical and psychosocial problems in the conduct of clinical trials (hereinafter: positive opinion of the Ethics Committee of Serbia). The positive opinion of the Ethics Committee of Serbia shall include the assessment referred to in item 4) of this paragraph;

- 4) The Ethics Committee of Serbia gave the opinion that the benefit of the use of a medical device that is clinically studied and its significance for the protection of the life and health of the subjects justify its possible risk;
- 5) That the right of the subjects to the physical and psychological integrity, privacy, as well as the protection of personal data in a clinical trial is ensured in accordance with the law regulating the protection of personal data;
- 6) Subject, or their legal representative, after being fully informed about the nature, significance and possible risks of the clinical trial in a comprehensible manner, gave informed consent. Informed consent must be given in written form, signed and dated by the subject, i.e. their legal representative and a member of the research team who conducted the informing of the subject;
- 7) Subject, or their legal representative, is fully informed in a comprehensible manner of the clinical trial and their right to withdraw their informed consent at any time;
- 8) Subject who is not literate, gave an oral informed consent to participate in a clinical trial in the presence of at least one impartial witness.

Clinical trial is carried out at the healthcare institution (hereinafter: clinical trial site) and by healthcare professionals employed at the clinical trial site, i.e. the principal investigator with a full-time employment and members of the research team who are employed or otherwise engaged at the clinical trial site in accordance with the law.

The principal investigator and members of the research team cannot undertake any activity related to the clinical trial prior to the approval for the conduct of the clinical trial issued by the Agency and the positive opinion of the Ethics Committee of Serbia.

Clinical trial may be performed only at the clinical trial site with which the sponsor has concluded the contract on the conduct of clinical trial.

The clinical trial site shall keep records of the conducted clinical trials for at least five years from the date of the end of the clinical trial.

5. Specific requirements for carrying out clinical trials on vulnerable groups

Article 33

In addition to the general requirements referred to in Article 32 of this Law, a clinical trial on vulnerable groups may be conducted if:

- 1) Subject, or their legal representative, give the informed consent;
- 2) Informed consent is given without incentive to participate in a clinical trial by offering or by giving any material or other benefit;

- 3) Informed consent given by the legal representative of the subject represents the presumed desire of the subject and the subject did not expressly refuse to participate in the clinical trial;
- 4) Subject, or their legal representative, was informed that the informed consent can be withdrawn at any time, without damage to the subject;
- 5) Subject comprehensively receives information related to the course of the clinical trial, the risks and benefits to their health, and the juveniles and persons deprived of working ability from a healthcare professional with experience in working with such persons;
- 6) The Ethics Committee of Serbia estimates that a clinical trial on the subject receives a direct benefit for a particular group of patients, and that such examination is essential for assessing the data obtained by clinical trials on individuals who are able to give informed consent;
- 7) The Ethics Committee of Serbia shall give a positive opinion, with particular reference to the clinical status of the subjects, ethical and psychosocial problems in the conduct of clinical trials and which shall include the assessment from item 6) of this paragraph.

If during the course of a clinical trial a juvenile becomes an adult, i.e. a person deprived of working ability gains the working ability, they must sign an informed consent before continuing their participation in a clinical trial.

6. A medical device that is clinically studied

Article 34

The medical device that is clinically studied must be manufactured in accordance with the essential requirements.

The provisions of this Law and the bylaws adopted for its implementation, which regulate the essential requirements for the manufacture of a medical device, shall also apply to the manufacture of a medical device intended for a clinical trial, unless otherwise provided by this Law and the regulations adopted for its implementation.

Article 35

Medical device which is clinically studied must be further labelled with the words: “for clinical trial”.

Article 36

The import of a medical device that is being clinically studied, as well as medicinal products and medical devices used in the conduct of a clinical trial, is carried out by the wholesale, based on the approval of the Agency for the conduct of the clinical trial and the authorisation of the sponsor.

An integral part of the approval by the Agency for the conduct of a clinical trial is a list of products used in carrying out a clinical trial, containing the name and quantity of the products.

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 wholesale shall be obliged to apply for the approval of the import of those products.

The authorisation referred to in paragraph 3 of this Article shall be issued by the Agency not later than ten days after the date of submission of the application.

7. The sponsor

Article 37

The sponsor may transfer part or all of its obligations regarding the conduct of a clinical trial to a contract research organisation with headquarters in the Republic of Serbia, which is responsible for the activities sponsored by the sponsor in the procedures for granting and conducting clinical trials on the territory of the Republic of Serbia.

The sponsor is responsible for the work it has transferred to the contracting research organisation.

A sponsor who does not have a head office in the Republic of Serbia must have a legal or natural person as a representative in the Republic of Serbia, who is responsible for the activities of the sponsor in the procedures for granting and conducting clinical trials on the territory of the Republic of Serbia.

The sponsor must have a person in charge of the documentation in the procedure for obtaining the approval for conducting the clinical trial, its amendments, as well as for the vigilance, with whom it is obliged to conclude a full-time employment contract, and to inform the Agency thereof.

Prior to the start of the clinical trial, the sponsor must insure the subjects in the event of the occurrence of damage arising from participation in the clinical trial, which corresponds to the purpose, nature and extent of the risk, in accordance with the law, and to determine the amount of the necessary expenses belonging to the subjects. The insurance policy must be valid for the entire duration of the clinical trial.

8. Request for approval of conduct of a clinical trial

Article 38

The request for approval of conduct of a clinical trial shall be submitted to the Agency with the documentation prescribed by this Law and the regulations adopted for its implementation.

The Agency shall approve the conduct of a clinical trial within 40 days from the date of receipt of the request.

If the request referred to in paragraph 1 of this Article is not complete, the Agency shall notify the applicant within 5 days from the date of receipt of the request to complete the request no later than within 20 days from the date of receipt of the notice.

The deadline for approving the conduct of a clinical trial referred to in paragraph 2 of this Article shall cease to run from the date when the Agency requests the supplementation of the request and continues to run from the date of submission of the requested information.

If the applicant fails to complete the request for approval of conducting a clinical trial within the time limit referred to in paragraph 3 of this Article, the Agency shall reject the application as incomplete.

The Agency shall publish on its website the issued authorisations for conducting a clinical trial within seven days from the date of issuance.

9. The opinion of the Ethics Committee of Serbia

Article 39

The Ethics Committee of Serbia shall give opinion on the clinical trial in the procedure that is being carried out in parallel with the approval of the Agency referred to in Article 38, paragraph 2 of this Law, within 30 days from the day of submitting the request.

If the request referred to in paragraph 1 of this Article is not complete, the Ethics Committee shall notify the applicant in written form to supplement the request with additional data no later than 15 days from the date of receipt of the notice.

The deadline for opinion of the Ethics Committee of Serbia on the clinical trial shall cease to run on the day the Ethics Committee of Serbia requests additional information and continues to run from the date of submission of the requested information.

If the applicant does not submit additional data within the deadline referred to in paragraph 2 of this Article, the request for opinion on the clinical trial shall be rejected by the Ethics Committee of Serbia as incomplete.

In addition to the members prescribed by the law regulating healthcare, the Ethics Committee of Serbia for the purpose of giving opinion on the clinical trial must have at least four doctors who are medical specialist with experience in scientific and medical evaluation of the results of clinical trials of medicinal products or medical devices, as well as ethical principles for clinical trial, as well as two representatives of the association of patients established at the level of the Republic of Serbia.

In addition to the majority of the total number of members of the Ethics Committee of Serbia defined by the law regulating healthcare, at least three doctors who are medical specialists and one representative of the association of patients referred to in paragraph 5 of this Article must attend the session of the Ethics Committee of Serbia where an opinion on the clinical trial shall be given.

The Ethics Committee of Serbia adopts opinion on the clinical trial by the majority of the total number of members present.

In the process of giving opinion on a clinical trial, only those members of the Ethics Committee of Serbia who are not investigators in a clinical trial on which a decision is made and who are independent of the sponsor and who have signed a statement on the absence of conflicts of private and public interest can give their opinion in accordance with the law.

In the process of giving opinions on a clinical trial, the Ethics Committee of Serbia may request the opinion of the ethics committee of the clinical trial site or the principal investigator on issues concerning the clinical trial site.

In the process of giving opinions on a Clinical trial, the Ethics Committee of Serbia may request the opinion of prominent experts, and who are not members of the ethics committee, from the specific fields that are necessary for giving opinions on clinical trials.

In the opinion on the clinical trial of the Ethics Committee of Serbia, all documents based on which the Ethics Committee of Serbia gave an opinion must be listed, including the versions and dates of the documents.

Opinion on a clinical trial of the Ethics Committee of Serbia must be signed and dated.

An integral part of the opinion on a clinical trial is a list of members who participated in giving that opinion.

The Ethics Committee of Serbia is obliged to act in accordance with this Law and the regulations adopted for its implementation in the procedure of giving opinion on the clinical trial and to apply the standards of good clinical practice guidelines in clinical trials.

If the Ethics Committee of Serbia mandate expired in accordance with the law regulating healthcare, the tasks of giving opinions on the clinical trials, until the appointment of a new Ethics Committee of Serbia, is carried out by the Ethics Committee of Serbia with expired mandate.

Administrative and technical tasks for the needs of the Ethics Committee of Serbia are performed by the Agency.

The expenses of the work of the Ethics Committee of Serbia are an integral part of the fee for providing services at the tariff referred to in Article 7, paragraph 1, item 2 of this Law.

10. Rejection of the application for authorisation to conduct a clinical trial

Article 40

The Agency shall reject the application for authorisation to conduct a clinical trial if it determines:

- 1) That the benefit of a medical device that is clinically studied is less 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 no preclinical tests have been completed;
- 3) That submitted documentation is not in accordance with the requirements prescribed by this Law and the regulations adopted for its implementation.

11. Amendments to the conduct of a clinical trial

Article 41

The sponsor is obliged to notify the Agency of amendments to the Protocol, i.e. the approval for conducting a clinical trial that are not essential, about which the Agency issues a certificate on the day of submitting the application.

If during the course of the clinical trial there are essential changes that can significantly affect the safety, i.e. the physical and psychological integrity of the subjects, the scientific value of the clinical trial, the further course of conduct of the clinical trial, as well as the conformity of the medical device which is clinically studied with the essential requirements, the sponsor is obliged to submit to the Agency a request for approval of an essential amendment to the Protocol, i.e. amendments to the approval for conducting a clinical trial (hereinafter: essential clinical trial amendments).

The Agency shall consider the request for the approval of the essential clinical trial amendments and shall make a decision within 30 days from the date of submission of the application.

If the request referred to in paragraph 2 of this Article is not complete, the Agency shall notify the applicant within five days from the date of receipt of the request to complete the request no later than ten days from the date of receipt of the notice.

The deadline for the approval of the essential clinical trial amendments shall cease to run from the date when the Agency requests the additional information from the sponsor and continues to run from the date of submission of the requested information.

If the applicant fails to submit the requested data within the deadline referred to in paragraph 4 of this Article, the Agency rejects the request for the approval of the essential clinical trial amendments as incomplete.

If the essential clinical trial amendments concern the issue to which the Ethics Committee of Serbia gave a positive opinion, the sponsor is obliged to obtain a positive opinion of the Ethics Committee of Serbia in addition to the approval of the essential clinical trial amendments by the Agency.

12. Approval of post-marketing interventional clinical trials

Article 42

The Agency shall approve conducting of the post-marketing interventional clinical trials in accordance with this Law and the regulations adopted for its implementation.

Provisions of Articles 29 to 41 of this Law shall also apply to the clinical trial of a medical device for which conformity assessment has been carried out, if the purpose of that trial is the use of a medical device for purposes not covered by an appropriate conformity assessment procedure.

13. Reporting of the post-marketing non-interventional clinical trial

Article 43

The sponsor is obliged to report to the Agency the conduction of the post-marketing non-interventional clinical trial.

The clinical trial referred to in paragraph 1 of this Article shall not require the approval of the Agency for conducting a clinical trial.

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

14. Reporting a serious adverse event in conducting a clinical trial

Article 44

If a serious adverse event occurs during the course of a clinical trial, the sponsor is obliged to immediately notify the Agency and the Ethics Committee of Serbia.

The Agency may propose to the Ministry to suspend or prohibit the conduct of a clinical trial in the cases referred to in paragraph 1 of this Article, especially if it has established that there has been a failure to comply with the relevant procedures in the Clinical Trials Protocol or guidelines of the good clinical practice.

The Ministry may suspend or prohibit the conduct of a clinical trial referred to in paragraphs 1 and 2 of this Article based on the performed inspection supervision in accordance with the law.

In the event of unexpected events that require the application of emergency security measures, the sponsor may instruct the investigators to apply these measures without the prior approval of the Agency.

In the case referred to in paragraph 4 of this Article, the sponsor shall notify the Agency without delay, and at the latest within seven days from the date of application of the security measures.

15. Control of the conduction of the clinical trial

Article 45

The control of the conduction of the clinical trial shall be performed by the Agency in accordance with this Law and the regulations adopted for its implementation, the Clinical Investigation Protocol and guidelines of the good clinical practice.

The sponsor may require the Agency to carry out the control of the conduction of the clinical trial at the clinical trial site.

16. Remedy of irregularities in the conduct of clinical trials

Article 46

In the procedure for controlling the conduct of a clinical trial at the clinical trial site, the Agency may in written form order that certain irregularities in the conduct of clinical trials are to be corrected within 30 days.

The Agency may propose to the Ministry to suspend or prohibit the conduct of a clinical trial if, within the deadline referred to in paragraph 1 of this Article, irregularities are not remedied, if it determines that the conduct of the clinical trial is not carried out in accordance with this Law and the regulations adopted for its implementation, Clinical Trial Protocol or guidelines of the good clinical practice.

The Ministry may suspend or prohibit the conduct of the clinical trial referred to in paragraph 2 of this Article on the basis of performed inspection in accordance with the law.

Decision of the Minister referred to in paragraph 3 of this Article is final in the administrative procedure and an administrative dispute can be initiated against it.

17. Suspension or prohibition of the clinical trial

Article 47

In order to protect the health and safety of subjects involved in clinical trials, the Agency may decide to terminate the validity of the approval for the conduct of a clinical trial.

If the Agency determines, on the basis of the performed control, that the initiated clinical trial should not be urgently suspended in order to protect the health of the subjects, i.e. the interests of science and the society as a whole, it is obligated to request additional information from the sponsor or the principal investigator on the conduct of the clinical trial.

The sponsor or the principal investigator is obliged to submit to the Agency all requested information within seven days from the date of requesting the information, on the basis of which the Agency informs the sponsor, the principal investigator and the Ethics Committee of Serbia about the proposed measures, in accordance with this Law.

18. Reporting on the course of the clinical trial

Article 48

The sponsor is obliged to report to the Agency on a quarterly basis on the course of conducting a clinical trial, and in case of early completion or termination of the clinical trial, the sponsor is obliged to notify the Agency and the Ethics Committee of Serbia within 15 days from the day of the interruption or early completion of the clinical trial, explaining why the clinical trial was stopped.

The sponsor is obliged to notify the Agency and the Ethics Committee of Serbia about the completion of the clinical trial within 90 days from the day the clinical trial was completed.

The sponsor is obliged to prepare a final report on the results of a clinical trial which it shall submit to the Agency within one year after the end of the clinical trial.

The report referred to in paragraph 3 of this Article must also contain the positive and negative results of the clinical trial, in a detailed and appropriately illustrated manner, so that it is possible to objectively assess the safety and performance, as well as the benefit-risk ratio of the use of a medical device.

Article 49

The sponsor is obliged to notify the Agency about the temporary suspension of the clinical trial for reasons that do not affect the benefit-risk ratio in conducting the clinical trial within 15 days from the decision to temporarily suspend the clinical trial.

If the sponsor does not initiate temporarily suspended clinical trial within two years from the date of the temporary suspension, the clinical trial will be deemed to have been completed.

If the sponsor decides to continue conducting the clinical trial, it shall submit to the Agency a request for essential clinical trial amendments.

IX REGISTRATION OF MEDICAL DEVICES

1. Register of medical devices

Article 50

The Agency carries out the registration of a medical device for which conformity assessment has been carried out, which is placed on the market or in the use (hereinafter: the Register of Medical Devices, unless otherwise provided by this Law.

Registration of a medical device in accordance with this Law shall not be a requirement for placing the medical device referred to in paragraph 1 of this Article on the market or in use.

The Minister prescribes the content of the request, documentation, as well as the manner of registration, renewal of the validity of registration, amendments and removal of a medical device from the Register of Medical Devices.

2. Applicant for registration

Article 51

The application for registration of a medical device prior to placing a medical device on the market, or in use, should be submitted by:

- 1) Manufacturer of medical device (manufacturer with seat in the Republic of Serbia or representative office or branch of foreign manufacturer with seat in the Republic of Serbia);
- 2) Authorised representative of the manufacturer.

The Applicant referred to in paragraph 1 of this Article shall, along with the request, submit the appropriate document of conformity, as well as other documentation prescribed by this Law and the regulations adopted for its implementation.

An authorisation in written form by a foreign medical device manufacturer must be signed by a foreign manufacturer and an authorised representative of the manufacturer and contain the obligations and tasks performed by the authorised representative of the manufacturer in the Republic of Serbia on behalf of that manufacturer, and in particular:

- 1) To keep the technical documentation, the certificate of conformity of the medical device and all the certificates for that medical device;
- 2) At the request of the Ministry or the Agency, provide and submit all data and documentation proving the compliance of the medical device;
- 3) To carry out corrective or preventive measures ordered by the Ministry or the Agency in order to eliminate the risks that may be caused by a medical device;
- 4) Inform the manufacturer without delay of all complaints, quality defects and incidents reported by the users of the medical device;

- 5) To submit without delay the request to the Agency to remove the data on the authorised representative from the Register of Medical Device Manufacturers if the manufacturer changes the authorised representative in the Republic of Serbia.

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.

The applicant referred to in paragraph 1 of this Article must have a person responsible for the documentation and a person responsible for the vigilance.

3. Registration of a medical device

Article 52

The Agency shall issue a decision on the registration of a medical device for a validity period of 60 days after the expiry date of the certificate of conformity.

For Class I medical devices (other than the Is and Im classes) and other *in vitro* diagnostic medical devices placed on the market on the basis of a Declaration of Conformity issued by the manufacturer, the decision on the registration of a medical device shall be granted for a period of five years from the date of issuance of the decision.

Medical devices may be on the market for a maximum of 90 days from the date of expiry of the decision on the registration of a medical device.

The import of the medical device is not possible for devices which registration has expired and the application for renewal of the registration was not submitted within the deadline referred to in paragraph 3 of this Article.

The Agency is obliged to perform the registration of a medical device that is in compliance with the essential requirements no later than 30 days from the date of submission of the request.

If the request for registration of a medical device is not complete, the Agency shall notify the applicant not later than within 15 days from the date of submission of the request to complete the request no later than 30 days from the date of receipt of the notification, in accordance with this Law and the regulations adopted for its implementation .

The deadline referred to in paragraph 5 of this Article shall cease to run from the date when the Agency requests additional information from the applicant and continues to run from the date of submission of the requested information.

The Agency is obliged to publish data on the registration of a medical device on its official website at the latest within seven days from the date of issuing the decision on the registration of a medical device.

4. Amendments to the registration of a medical device

Article 53

The manufacturer, or an authorised representative of the manufacturer, is obliged to submit a request, or application for each amendment of data from the Register of Medical Devices.

The request for amendments by the authorised representative of the manufacturer to the Agency shall be submitted by the manufacturer or a new authorised representative of the manufacturer without delay.

The Agency shall issue a decision on the amendments to the registration of a medical device within 15 days from the date of submission of the request.

Amendments to the registration that do not affect the safety and performance of a medical device are reported to the Agency.

Amendments to the registration referred to in paragraph 4 of this Article shall be entered in the Register of Medical Devices without issuing the decision referred to in paragraph 3 of this Article, with notification of the Applicant.

If the request referred to in paragraph 1 of this Article is not complete, the Agency shall notify the applicant not later than within ten days from the date of submission of the request to complete the request no later than 15 days from the date of receipt of the notice in accordance with this Law and the regulations adopted for its implementation.

The deadline referred to in paragraph 3 of this Article shall cease to run from the date when the Agency requests additional information from the applicant and continues to run from the date of submission of the requested information.

The Agency is obliged to publish the amendments to registration on its official website no later than seven days from the day of issuing the decision on amendments to registration of a medical device.

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

The manner of change of the authorised representative of the manufacturer is defined by the contract, which is, as a rule, concluded between the manufacturer, the existing and the future authorised representative, and which must contain at least:

- 1) The date of termination of the mandate of the existing authorised representative and the start date of the mandate of the future authorised representative;

- 2) The date by which the existing authorised 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 authorised representative to submit to the manufacturer or future authorised representative, after the expiry of the mandate, any complaint, quality and incidental defect, submitted by healthcare professionals, patients, or users of the medical device for which it was designated as an authorised representative.

5. Renewal of registration of a medical device

Article 54

The manufacturer or the authorised representative of the manufacturer is obliged to submit to the Agency a request for the renewal of the registration of a medical device at least 30 days before the expiration of the decision on the registration of the medical device.

The Agency is obliged to issue a decision on the renewal of the registration of a medical device no later than 15 days from the date of receipt of the request, and on the basis of the valid document of conformity and other documentation prescribed by this Law and the regulations adopted for its implementation.

If the request referred to in paragraph 1 of this Article is not complete, the Agency shall notify the applicant not later than within ten days from the date of submission of the request to complete the request no later than 15 days from the date of receipt of the notification in accordance with this Law and the regulations adopted for its implementation .

The deadline referred to in paragraph 2 of this Article shall cease to run from the date when the Agency requests additional information from the applicant and continues to run from the date of submission of the requested information.

If the Agency does not issue a decision on renewal of registration of a medical device within the deadline referred to in paragraph 2 of this Article, it is considered that a medical device may be placed on the market in accordance with a previously issued decision on the registration of a medical device.

The manufacturer or authorised representative of manufacturer shall be responsible for the vigilance and quality defect of the medical device referred to in paragraph 5 of this Article, as well as the compliance with the essential requirements.

The Agency is obliged to publish the renewal of the registration of a medical device on its official website at the latest within seven days from the day of issuing the decision on the renewal of the registration of a medical device.

The manufacturer or the authorised representative of the manufacturer is obliged to place a medical device on the market within the period of 12 months from the date of delivery of the decision referred to in paragraph 2 of this Article in accordance with this decision.

In the case referred to in paragraph 5 of this Article, the Agency shall be obliged to notify the competent inspection.

The renewal of the registration of a medical device may also include amendments to the registration of that medical device, at the request of the manufacturer or the authorised representative of the manufacturer.

6. Medical devices that are not registered in the Register of Medical Devices

Article 55

The following medical devices shall not be registered:

- 1) For which the approval for conducting a clinical trial has been issued;
- 2) Which is intended for the continuation of treatment initiated outside the territory of the Republic of Serbia for the personal use of a particular patient upon the proposal of the competent healthcare professional in the country in which the treatment was started;
- 3) Which is a custom made device;
- 4) Which is intended for scientific research and development;
- 5) Which, for the purpose of displaying at exhibitions and fairs, are temporarily imported;
- 6) Which is manufactured in a health institution for use in that healthcare institution in accordance with this law.

7. Removal of a medical device from the Register of Medical Devices

Article 56

The Agency is obliged to issue a decision on the removal of a medical device from the Register of Medical Devices, without delay, if:

- 1) The medical device is not safe under prescribed conditions of use;
- 2) The data on the medical device in the Register of Medical Devices is incorrect or not complete;
- 3) The information on the manufacturer or the authorised representative of the manufacturer in the Register of Medical Devices is incorrect or not complete;
- 4) On the proposal of the Ministry, in the case referred to in Article 21 of this Law;
- 5) At the request of the manufacturer or the authorised representative of the manufacturer.

If no request for renewal of registration of a medical device is submitted in accordance with Article 54 of this Law, the Agency shall remove the medical device from the Register of Medical Devices without issuing the decision referred to in paragraph 1 of this Article.

The authorised representative of the manufacturer whose mandate ceased or expired shall be obliged to submit to the Agency, without delay, the request for removal from the Register of Manufacturers.

The Agency shall execute the removal of registration of a medical device on its official website within seven days from the date of issuance of the removal decision from the Register of Medical Devices.

X MANUFACTURE OF THE MEDICAL DEVICE

1. Manufacturer

Article 57

A legal or natural person who meets the requirements prescribed by this Law and the regulations adopted for its implementation may perform the manufacture of a medical device in the Republic of Serbia.

A legal or natural person who compiles or adapts a medical device for a particular purpose that is on the market and is intended for a particular patient is not considered a manufacturer within the meaning of the provisions of this law.

2. Obligations of the manufacturer

Article 58

The manufacturer is obliged to manufacture medical devices in accordance with the essential requirements.

The manufacturer is obliged to:

- 1) Provide conditions in terms of space and equipment for manufacture in accordance with the essential requirements for the medical device the manufacture whereof is performed;
- 2) That a full-time employee is responsible for manufacture and a qualified person responsible for quality and vigilance;
- 3) Ensure that the medical device is designed in accordance with the essential requirements;
- 4) Classify a medical device in the appropriate risk class, prepare the prescribed technical documentation and implement, or ensure the implementation of an applicable conformity assessment procedure;
- 5) Make a declaration of conformity, where applicable, and mark the medical device with a sign of conformity in accordance with this Law and the regulations adopted for its implementation, or make a statement under Article 19, paragraph 1 of this Law;
- 6) 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;

- 7) Provide procedures to ensure the maintenance of the conformity of manufacture of a medical device;
- 8) Mark the medical device and attach the instruction manual in accordance with this Law and the regulations adopted for its implementation;
- 9) Take necessary corrective measures in case of established non-compliance;
- 10) That for a medical device, except for a medical device manufactured on a custom made device or intended for clinical examination, it establishes and maintains a plan for monitoring the medical device after placing it on the market, which involves the collection, analysis and investigation of each complaint, quality defects and incidents related to the medical device that are reported by the users of the medical device, as well as to keep records of non-compliant and medical devices withdrawn from the market.

The manufacturer is obliged to provide insurance against damage that may occur when using a medical device, in accordance with the law.

3. Issuing a license for the manufacture of a medical device

Article 59

The Ministry issues a manufacture licence for a class I medical device (other than the Is and Im class), other in vitro diagnostic medical devices, as well as a medical device for which no conformity assessment is performed, that is not covered by the sign of conformity, or for a medical device manufactured on a custom-made device or for a clinical examination, as well as a system or kit in accordance with this Law and the regulations adopted for its implementation.

The request for obtaining the manufacture licence referred to in paragraph 1 of this Article shall be submitted in writing and shall contain:

- 1) The name of the manufacturer, the address of the seat and place of manufacture;
- 2) A description of the medical devices to be manufactured;
- 3) A description of the procedure or part of the manufacturing process of the medical devices for which the permit is sought;
- 4) The name of the person responsible for the manufacture and the name of the person responsible for quality and vigilance;
- 5) List of equipment for manufacture with certificates, or technical data on equipment;
- 6) Information on the handling of waste products and environmental protection;
- 7) Other information significant for obtaining a manufacturing licence.

The request referred to in paragraph 2 of this Article shall be submitted to the Ministry.

The Minister shall prescribe the conditions for the manufacture of medical devices, the manner of issuing the permit, or amendments and renewals, as well as the content of the manufacturing licence.

The minister's decision referred to in paragraph 1 of this Article is final in the administrative procedure and an administrative dispute can be initiated against it.

Article 60

The Ministry shall issue a licence for the manufacture of a medical device within 60 days from the date of receipt of the request referred to in Article 59, paragraph 2 of this Law, if the conditions prescribed by this Law and the regulations adopted for its implementation are fulfilled.

If the request referred to in Article 59, paragraph 2 of this Law is not complete, the Ministry shall inform the applicant in writing, to submit the requested data in written form within 15 days from the date of receipt of the notification.

The time limit referred to in paragraph 1 of this Article shall cease to run from the date when the Ministry requests, in writing, additional information from the applicant to be delivered in written form no later than 15 days of the date of submission of the requested information.

The authorisation for the manufacture of a medical device may relate to the entire process or parts of the manufacturing process of the medical device.

A licence for the manufacture of a medical device is issued for a period of five years.

The manufacturer to whom the manufacture licence is issued shall be obliged to carry out the manufacture of a medical device in accordance with the manufacturing licence.

4. Amendments, supplements and renewal of the manufacturing authorisation of a medical device

Article 61

If the holder of a manufacturing authorisation of a medical device changes or amends the conditions from the manufacturing licence, they are obliged to submit a request in writing to the Ministry for amending or supplementing the licence for the manufacture of a medical device.

On the basis of verification of data from the request referred to in paragraph 1 of this Article, the Ministry shall issue a decision on amending or supplementing the license for the manufacture of a medical device within 30 days from the date of receipt of the request.

If the request referred to in paragraph 1 of this Article is not complete, the Ministry shall inform the applicant in writing, to submit the requested data in written form within 15 days from the date of receipt of the notification.

The time limit referred to in paragraph 2 of this Article shall cease to run from the date when the Ministry requests additional information from the applicant and continues to run from the date of submission of the requested information.

Prior to the expiration of the period for issuing a licence for the manufacture of medical devices, the manufacturer of medical devices in the Republic of Serbia shall be obliged in writing to submit to the Ministry a request for renewal of the manufacture licence in accordance with this Law and the regulations adopted for its implementation.

Based on verification of data from the request referred to in paragraph 5 of this Article, the Ministry shall issue a decision on renewal of the licence for the manufacture of a medical device no later than 30 days from the date of receipt of the request.

If the request referred to in paragraph 5 of this Article is not complete, the Ministry shall inform the applicant in writing, to submit the requested data in written form within 15 days from the date of receipt of the notification.

The time limit referred to in paragraph 3 of this Article shall cease to run from the date when the Ministry requests additional information from the applicant and continues to run from the date of submission of the requested information.

The minister's decision referred to in paragraph 2 of this Article is final in the administrative procedure and an administrative dispute can be initiated against it.

5. Annulment of the decision granting a licence for the manufacture of a medical device

Article 62

The Ministry may issue a decision terminating the decision granting a licence for the manufacture of a medical device if:

- 1) The manufacturer does not perform manufacture in accordance with the manufacture permit, or if they change the conditions on the basis of which the licence for the manufacture of a medical device has been issued, in accordance with this law and the regulations adopted for the implementation of this law, and does not inform the Ministry thereof;
- 2) The manufacturer ceases to fulfil the conditions prescribed by this Law and the regulations adopted for its implementation;
- 3) They fail to remedy deficiencies and irregularities in the work determined by the competent inspectorate in accordance with this Law within a specified period;
- 4) The manufacturer submits a request for the cessation of validity of the manufacturing licence.

By issuing the decision referred to in paragraph 1 of this Article, the licence for the manufacture of a medical device shall cease to be valid.

The minister's decision referred to in paragraph 1 of this Article is final in the administrative procedure and an administrative dispute can be initiated against it.

6. Registration of the manufacturer or authorised representative of the manufacturer

Article 63

The Agency is obliged, within seven days from the date of issuing the decision on registration of a medical device, to register the manufacturer or the authorised representative of the manufacturer (hereinafter: the Register of Manufacturers).

For the medical device referred to in Article 59, paragraph 1 of this Law, the information about the manufacturer or the authorised representative of the manufacturer to the Agency shall be submitted by the Ministry for registration in the Register of Manufacturers.

For a manufacturer who, on their own behalf, places on the market, that is, into service Class I medical devices, as well as other in vitro diagnostic medical devices, other than a medical device manufactured to a custom-made device and a medical device intended for clinical trials, in accordance with this Law and the regulations adopted for its implementation, as well as for any legal or natural person performing activities referred to in Article 25 of this Law, the Agency shall enter in the Register of Manufacturers the address of the place of manufacture of the medical device and on the classes and categories of these medical devices.

Legal entities or natural persons in the territory of the Republic of Serbia who, for the needs of a manufacturer outside the territory of the Republic of Serbia, perform manufacture or part of the manufacture of a medical device (service manufacture), as well as persons who perform manufacture or part of the manufacture of a medical product exclusively for export purposes, shall report to the Ministry the activity of manufacture.

Data from paragraphs 2, 3 and 4 of this Article shall be entered into an electronic database maintained by the Agency.

The Minister shall prescribe the content and manner of keeping the Register of Manufacturers, as well as the data from the Register of manufacturers, published on the official website of the Agency.

Article 64

The Agency is obliged to publish the Register of Manufacturers on its official website within seven days from the day of issuing the decision on the registration of a medical device.

At the request of the manufacturer, or other legal or natural persons having a legal interest, the Agency shall issue a certificate of data entered in the Register of Manufacturers.

Article 65

The manufacturer or the authorised representative of the manufacturer shall be obliged to report to the Agency any changes or amendments to the data entered in the Register of Manufacturers.

The Agency shall register changes or supplements to the data in the Register of Manufacturers not later than seven days from the date of receipt of the application referred to in paragraph 1 of this Article.

Article 66

The Agency shall remove the manufacturer or the authorised representative of the manufacturer from the Register of Manufacturers:

- 1) On their reasoned request;
- 2) Ex officio, if it finds that the manufacturer or the authorised representative of the manufacturer is registered in the Register of Manufacturers contrary to the provisions of this Law and the regulations adopted for its implementation;
- 3) In the case referred to in Article 21 of this Law, upon proposal of the Ministry.

The Agency shall remove the manufacturer or the authorised representative of the manufacturer from the Register of Manufacturers not later than 15 days from the day of obtaining the conditions referred to in paragraph 1 of this Article.

7. Performing the manufacture of a medical device

Article 67

The manufacture of a medical device cannot be carried out:

- 1) If it is not compliant with the essential requirements;
- 2) By a legal or natural person who does not meet the essential requirements;
- 3) By a legal or natural person to whom the Ministry did not issue a licence for the manufacture or renewal of a licence for the manufacture of a medical device, in accordance with this Law and the regulations adopted for its implementation;
- 4) By an unregistered entity in accordance with the law;
- 5) A falsified medical device.

8. Notifying the Ministry or the Agency

Article 68

The manufacturer or the authorised representative of the manufacturer shall, at the request of the Ministry or the Agency, submit a report on the manufacture, stocks, and the volume of sales for all individual medical devices (by packaging) in the Republic of Serbia.

The report referred to in paragraph 1 of this Article is a business secret, and the processed data on the total sale of medical devices is available to the public.

The manufacturer or an authorised representative of the manufacturer is obliged to submit to the Ministry a list of medical devices from his program that will supply the market in the Republic

of Serbia in the next calendar year for which they received a decision on entry in the Register of Medical Devices no later than October 1 of the current year.

The manufacturer or the authorised representative of the manufacturer shall be obliged to carry out continuous supply of the market with medical devices from the list of medical devices referred to in paragraph 3 of this Article.

XI MEDICAL DEVICES MARKETING

1. Volume of Marketing

Article 69

Marketing of medical devices includes wholesale and retail of medical devices in accordance with this Law and the regulations adopted for its implementation.

The wholesale of medical devices in the sense of this law is the purchase and further sale to natural or legal persons for the performance of their professional or registered activity, including import, export, procurement, storage and distribution, except for the issue of a medical device to the patient for their personal needs.

A medical device may be on the market, or in use, only if it meets the essential requirements, if a conformity assessment has been carried out and it is marked with a sign of compliance, and a medical device for which no conformity assessment is performed on the basis of a manufacture licence issued by the Ministry, in accordance with this Law and the regulations adopted for its implementation.

Every legal and natural person, state body, conformity assessment body, as well as any person who in any way comes into possession of a medical device, shall ensure that its transport, storage and keeping is carried out in accordance with the conditions prescribed by this Law and the regulations adopted for its implementation.

The use of a medical device in a health institution shall not be considered as marketing of a medical device within the meaning of this Law.

Transit or import for exporting a medical device is not considered trade within the meaning of this Law.

Export for the repair of a medical device of a certain serial number that was in use in the Republic of Serbia and the import of that medical device of the same serial number is not considered trade within the meaning of this Law.

The conditions for the marketing of medical devices by remote selling are prescribed by the Government.

2. Wholesale medical supplies

Article 70

The turnover, or part of the wholesale distribution of medical devices, can be performed by a legal or natural person that meets the requirements prescribed by this Law and the regulations adopted for its implementation (hereinafter: wholesale).

Wholesale may entrust certain tasks of the marketing of medical devices to a large wholesale market.

Certain tasks of wholesale of medical devices, in accordance with this Law and the regulations adopted for its implementation, may also be entrusted by wholesale to a legal or natural person who is not wholesale.

A manufacturer based in the Republic of Serbia who, in accordance with this Law, may issue a manufacturing licence to a large number of medical devices from his own manufacture program. A manufacturer with a head office in the Republic of Serbia who, in accordance with this Law, does not issue a manufacture licence, is obliged to apply for a marketing authorisation for a wide range of median funds from their own manufacture programme.

Wholesale is obliged to carry out the wholesale distribution of medical devices in accordance with the licence for wholesale medical devices and the guidelines for good practice in the distribution of medical devices.

The provisions of this Law and the bylaws adopted for its implementation regulating the wholesale distribution of medical devices shall apply *mutatis mutandis* to wholesale medical supplies from donations or humanitarian aid.

The Minister shall prescribe the conditions for the performance of the Marketing, that is, part of the turnover of medical devices in bulk, the manner and conditions for entrusting the tasks referred to in paragraph 2 and 3 of this Article, the method of issue, as well as the content of the licence for the wholesale distribution of medical devices.

The guidelines of good practice in the distribution of medical devices are prescribed by the Minister.

1) Requirements for issuing a marketing authorization for medical devices in bulk

Article 71

A legal or natural person who meets the requirements regarding space, equipment, personnel, as well as other requirements prescribed by this Law and the regulations adopted for its implementation may perform the wholesale distribution of medical devices.

The Ministry shall issue a licence for the wholesale distribution of medical devices to the person referred to in paragraph 1 of this Article.

A wholesale distribution licence for medical devices is issued for all or some of the activities referred to in Article 69, paragraph 2 of this Law, which includes wholesale trade.

Wholesale referred to in paragraph 1 of this Article shall have:

- 1) The person responsible for receiving, storing, keeping and delivering medical devices (hereinafter: a person responsible for the wholesale distribution of medical devices);
- 2) Adequate space, equipment and staff, as well as other conditions for the wholesale of medical devices.

With the persons referred to in paragraph 4, item 1) of this Article, wholesale shall be obliged to conclude a full-time employment contract.

Wholesale is obliged to ensure the permanent availability of the person referred to in paragraph 4, item 1) of this Article, or it may also determine other persons with the appropriate professional qualifications who have the authority for carrying out the work of that person.

The conditions referred to in paragraph 1 of this Article must also be met by the customs warehouse in which the medical devices are stored (warehousing), and which performs the activity in accordance with the customs regulations.

The Ministry shall give an opinion on the fulfilment of the conditions referred to in paragraph 7 of this Article, based on which the customs authority issues the approval for warehouse management.

2) Application for issue of a licence for the wholesale distribution of medical devices

Article 72

The application for the granting of a marketing authorisation for wholesale medical devices shall be submitted to the Ministry in writing.

The request referred to in paragraph 1 of this Article shall contain at least:

- 1) The name and seat of the legal or natural person and the place of storage of medical devices;
- 2) A list of classes and categories of medical devices for which the wholesale market requires permission;
- 3) The name of the person responsible for the wholesale distribution of medical devices;
- 4) Statement on the territory of supply with medical devices;
- 5) Plan for urgent withdrawal of medical devices from the market.

The Minister shall prescribe more precisely the contents of the requests and documentation for the issue of a marketing authorisation for wholesale medical devices.

3) Issue a licence for the wholesale distribution of medical devices

Article 73

The Ministry shall issue a licence for the wholesale distribution of medical devices at the latest within 60 days from the date of receipt of the application for the issue of a marketing authorisation for wholesale medical devices, if the conditions prescribed by this Law and the regulations adopted for its implementation are fulfilled.

If the request referred to in paragraph 1 of this Article is not complete, the Ministry shall inform the applicant in writing, to submit the requested data in written form within 15 days from the date of receipt of the notification.

The time limit referred to in paragraph 1 of this Article shall cease to run from the date when the Ministry requests additional information from the applicant and continues to run from the date of submission of the requested information.

The licence referred to in paragraph 1 of this Article shall be issued for a period of five years.

The Minister's decision referred to in paragraph 1 of this Article is final in the administrative procedure and an administrative dispute can be initiated against it.

4) Register of issued licences for wholesale medical devices

Article 74

The Register of Licences issued for the wholesale distribution of medical devices (hereinafter: the Register of Wholesale) in electronic form is established and maintained by the Serbian Chamber of Commerce, as a trusted job.

The wholesale register that imports medical devices from non-EU countries (hereinafter: the Register of Importers) in electronic form is established and maintained by the Serbian Chamber of Commerce as a trusted job.

The Serbian Chamber of Commerce, at the request of wholesalers, or other legal or natural persons having an indisputable legal interest, shall issue a certificate on the data kept in the register referred to in paragraph 1 and 2 of this Article.

The Minister shall prescribe which data shall be entered in the registers referred to in paragraphs 1 and 2 of this Article, as well as the method of entry.

5) Amendments, supplements and renewal of the marketing authorisation for medical devices in bulk

Article 75

If wholesale changes or supplements the conditions from the licence for the wholesale distribution of medical devices, it is obliged to submit to the Ministry in writing a request for amendment or supplementation of the license.

Based on the verification of data from the request referred to in paragraph 1 of this Article, the Ministry shall issue a decision on amending or supplementing the licence for the wholesale distribution of medical devices at the latest within 30 days from the date of receipt of the request.

If the request referred to in paragraph 1 of this Article is not complete, the Ministry shall inform the applicant in writing, to submit the requested data in written form within 15 days from the date of receipt of the notification.

The time limit referred to in paragraph 2 of this Article shall cease to run from the date when the Ministry requests additional information from the applicant and continues to run from the date of submission of the requested information.

Before the expiration of the period for issuing a licence for the wholesale distribution of medical devices, wholesale must submit a request in writing to the Ministry for renewal of the licence in accordance with this Law and the regulations adopted for its implementation.

Based on the verification of data from the request referred to in paragraph 5 of this Article, the Ministry shall issue a decision on renewal of the licence for the wholesale distribution of medical devices at the latest within 30 days from the date of receipt of the complete request.

If the request referred to in paragraph 5 of this Article is not complete, the Ministry shall inform the applicant in writing, to submit the requested data in written form within 15 days from the date of receipt of the notification.

The time limit referred to in paragraph 6 of this Article shall cease to run from the date when the Ministry requests additional information from the applicant and continues to run from the date of submission of the requested information.

The decision of the Minister from paragraphs 2 and 6 of this Article is final in the administrative procedure and an administrative dispute can be initiated against it.

6) Annulment of the marketing authorisation for medical devices in bulk

Article 76

The Ministry may issue a decision on the revocation of a decision granting a licence for the wholesale distribution of medical devices if wholesale does not trade wholesale medical devices in accordance with the licence for wholesale trade issued in accordance with this Law and the regulations adopted for its implementation, or if it amends the conditions or does not renew the licence for the wholesale distribution of medical devices, and does not inform the Ministry thereof.

By the adoption of the decision referred to in paragraph 1 of this Article, the marketing authorisation for medical devices shall cease to be valid.

The minister's decision referred to in paragraph 1 of this Article is final in the administrative procedure and an administrative dispute can be initiated against it.

7) Reasons for revocation of the licence for the wholesale distribution of medical devices

Article 77

The Ministry may issue a decision on termination of the decision whereby the wholesale licence is issued for wholesale trade, if wholesale:

- 1) Ceases to fulfil the conditions for the wholesale distribution of medical devices on the basis of which the decision prescribed by this Law and the regulations adopted for its implementation has been issued;
- 2) Fails to remedy deficiencies and irregularities in the work determined by the Ministry in accordance with this Law and the regulations adopted for its implementation within a specified period;
- 3) Fails to perform the obligation of continuous supply of the market with a medical device for which a wholesale permit has been issued, in accordance with this Law and the regulations adopted for its implementation;
- 4) Submits a request for revocation of the wholesale licence;
- 5) Performs the wholesale turnover of forged medical devices or if they do not inform the Ministry, the Agency and the manufacturer or the authorised representative of the manufacturer about the sale of a medical device suspected of being forged or found to be falsified.

If the private customs warehouse for medical devices ceases to fulfil the conditions for storage of medical devices for which the licence has been issued in accordance with Article 71, paragraph 7 and 8 of this Law, the Ministry shall inform the customs authority that issued the decision on the opening of the customs warehouse.

8) Control of compliance with the guidelines of good practice in distribution

Article 78

The Ministry, in the procedure of regular and extraordinary supervision, assesses the compliance of the wholesale distribution of medical devices with the guidelines of good practice in the distribution in accordance with this Law and the regulations adopted for its implementation.

If it determines a critical mismatch in the wholesale distribution of medical devices with guidelines for good practice in distribution, the Ministry shall take all necessary measures for the protection of public health immediately.

If it determines a critical inconsistency in the wholesale distribution of medical devices with guidelines for good practice in distribution that may affect the quality of the medical device on the market, the Ministry may request an extraordinary assessment of the compliance of the medical device sampled at the wholesale site of the appropriate designated or authorised body.

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

In the event that the Ministry determines a critical lack of compliance with the wholesale distribution of medical devices with guidelines for good practice in distribution, it may terminate the decision granting the license for the wholesale distribution of medical devices.

In case of determining minor inconsistencies in the performance of the wholesale Marketing of medical devices with guidelines for good practice in distribution, the Ministry may impose a measure of removing non-conformity (hereinafter: corrective measures) and determine wholesale to eliminate the identified nonconformities within 30 days at the latest.

3. Import of a medical device that is not registered in the Republic of Serbia

Article 79

The Agency may, exceptionally, authorise the import of a medical device that is not registered in the Republic of Serbia, which is intended for a particular patient or group of patients, the import of a medical device as a donation or humanitarian aid, or a donation programme in the European Union, a medical instrument for scientific research and in case of an emergency situation in accordance with the law.

The medical device referred to in paragraph 1 of this Article must be subjected to conformity assessment, i.e. an equivalent safety and performance assessment in accordance with this Law and the regulations adopted for its implementation.

The Minister shall prescribe the conditions and manner of importing medical devices that are not registered in the Republic of Serbia.

Importers' obligations

Article 80

The importer of a medical device from non-EU countries may place on the market only a medical device for which a conformity assessment has been carried out in accordance with this Law and the regulations adopted for its implementation.

Before placing the medical device on the market, the importer is obliged to provide:

- 1) That the manufacturer has carried out an appropriate procedure for assessing the conformity of the medical device they import;
- 2) That the manufacturer has authorised an authorised representative in accordance with this Law;
- 3) That the manufacturer has prepared a declaration of conformity and technical documentation on the medical device they import;
- 4) That the medical device is marked with a sign of conformity in accordance with this Law;
- 5) That the medical device is marked in accordance with this Law and the regulations adopted for its implementation and accompanied by the instructions for use and the declaration of conformity;
- 6) That the manufacturer has given the medical device a unique medical identification number (UDI) or bar code, if applicable.

The Minister shall prescribe the conditions and manner of importing medical devices from non-EU countries more closely.

4. The obligation of continuous supply of the market

Article 81

Wholesale is obliged to provide continuous supply of the market with medical devices in accordance with the licence for the wholesale distribution of medical devices.

Wholesale is obliged, upon request of a medical institution, private practice, specialised medical device shop, as well as other organisations authorised to provide health care in accordance with the law, deliver the medical device for which it was granted a wholesale license in the shortest time which poses no risk to human life and health, or public health.

Wholesale is obliged to provide the necessary supplies of medical devices for which the wholesale market has been granted a permit, or to commence the procurement or import in a timely manner, in order to prevent the interruption of market supply.

Wholesale is obliged to conclude a contract with all manufacturers, or authorised representatives of the manufacturer, or be authorised to carry out wholesale trade of medical devices of these manufacturers, or authorised representatives of manufacturers, and at the request of the Ministry to submit a list of manufacturers or authorised representatives of the manufacturer.

5. Carrying out marketing of a medical device

Article 82

No medical device shall be marketed:

- 1) Which is not harmonised with the essential requirements, or for which no conformity assessment has been carried out in accordance with this Law and the regulations adopted for its implementation;

- 2) For which a request for registration has not been submitted in accordance with this Law;
- 3) Manufactured by a legal entity or a natural person not registered in the Register of Manufacturers, or to whom the Ministry has not issued a manufacture licence in accordance with this Law and the regulations adopted for its implementation;
- 4) By a legal or natural person other than wholesale, unless otherwise provided by this Law;
- 5) By an unregistered entity;
- 6) Which is not marked with a sign of conformity, that is not marked in accordance with this Law and the regulations adopted for its implementation;
- 7) Which does not have the corresponding certificate of conformity;
- 8) To which the expiry date has been indicated on the packaging or an irregularity has been established in respect of its prescribed quality;
- 9) A falsified medical device, as well as a medical device for which there is a reasonable suspicion that it is forged;
- 10) A medical device that is not registered in the Republic of Serbia, and whose import is not authorised in accordance with Article 79 of this Law;
- 11) By remote selling (e.g. via mail and the Internet);
- 12) Made in a health institution for use in that medical institution in accordance with this Law.

Wholesale is obliged to physically separate every falsified medical device from other medical devices immediately, and to take all measures to prevent it from being re-marketed.

Wholesale is obliged to inform the Ministry, the Agency, the manufacturer, or the authorised representative of the manufacturer immediately, of the Marketing of the forged medical device as well as a medical device for which there is a reasonable doubt that it has been forged.

Marketing and transit of forged medical devices shall not be performed.

Article 83

The manufacturer is obliged to sell medical devices from their manufacture programme only to persons who have a licence for wholesale medical devices, pharmacies, other health institutions, private practice, specialised medical equipment shops, veterinary organisations, as well as other organisations authorised to provide health care in accordance with the law.

Wholesale is obliged to trade medical devices only to persons who have a licence for wholesale medical devices, pharmacies, other health institutions, private practice, specialised medical equipment shops, veterinary organisations, as well as other organisations authorised to provide health care in accordance with the law.

Exceptionally from paragraphs 1 and 2 of this Article, the manufacturer and wholesaler may trade certain medical devices to other legal entities that perform retail trade at closed points of sale in accordance with the regulations governing trade.

Under certain medical devices referred to in paragraph 3 of this Article, medical devices whose issue or sale by a decision on the registration of a medical device are also envisaged at other

closed retail outlets in which retail trade is performed in accordance with the regulations governing trade.

Wholesale is required to purchase medical supplies directly from the manufacturer, authorised representative of the manufacturer or other wholesaler.

The pharmacy, or private practice, as well as a specialised medical equipment shop, is obliged to only trade medical devices for retail purposes for the needs of patients.

The sale or sale of retail medical devices shall be made only in pharmacies, other healthcare institutions, private practice, specialised shop, as well as in other places designated by the Agency, unless this law, the law regulating healthcare and the law regulates health insurance is not otherwise regulated.

6. Withdrawal of the medical device from the market

Article 84

The Ministry prohibits Marketing and requires that the medical device be withdrawn from the market:

- 1) If a particular medical device is harmful under the normal conditions of use, at the proposal of the Agency or on the basis of a notification received from the designated body;
- 2) If it fails to fulfil its performance at the proposal of the Agency or on the basis of a notification received from the designated body;
- 3) If the benefit-risk relationship is not favourable under approved conditions of application, at the proposal of the Agency;
- 4) If its qualitative and quantitative composition does not correspond to the composition prescribed by the manufacturer, at the proposal of the Agency or on the basis of a notification received from the designated or authorised body;
- 5) If the prescribed conformity assessment procedures have not been carried out ex officio, or on the proposal of the designated body;
- 6) If it is manufactured by a legal entity or a natural person that is not registered in the Register of Manufacturers, or to whom the Ministry has not issued a production license;
- 7) If a request for registration has not been submitted for a medical device;
- 8) If there is no corresponding certificate of conformity;
- 9) At the proposal of the Agency if a medical device that is on the market is forged or suspected of being forged;
- 10) If the expiry date of the medical device has passed;
- 11) In other cases when the medical device is on the market contrary to the conditions prescribed by this Law and the regulations adopted for its implementation.

In the case referred to in paragraph 1 of this Article, the Ministry may fully withdraw the medical device from the market or only a certain series of medical devices.

The Ministry may order the withdrawal of a medical device, or a certain series of medical devices from the market, on the basis of a notice received through an international system for the rapid exchange of information on unsafe products of the European Union, the EEA and the State with which the European Union has a Mutual Recognition Agreement (MRA) foreign bodies or institutions of these States in charge of medical devices, Pharmaceutical Inspection Co-operation Scheme (PIC/S), if the notice contains a proposal of measures and activities undertaken in relation to a serious risk the medical device represents for public health and safety of the user.

Wholesale is obliged to withdraw the medical device from the market, or stop the wholesale distribution of medicines for which the Ministry imposed a ban on Marketing and withdrawal from the market.

In the event that the manufacturer, or an authorised representative of the manufacturer, decides to withdraw from the market a medical device or a certain series of medical devices, shall inform the Ministry and the Agency without delay.

In the case of a medical device which is not registered in the Republic of Serbia and which is placed on the market in accordance with this Law and the regulations adopted for its implementation, the importer of that medical device shall be responsible for withdrawing the medical device from the market and taking measures to prevent it from being marketed, as well as the person responsible for vigilance at the importer.

The Ministry and the Agency publish information on the measures and activities that are undertaken in relation to the serious risk that the medical device represents for public health and safety of the users on their website.

The Minister shall prescribe the manner of suspension of Marketing, the withdrawal of a medical device from the market, and the manner of notification of suspension and withdrawal.

7. Records

1) The contents of the records

Article 85

Wholesale is obliged to keep records on the type, number or quantity of sold medical devices in the Republic of Serbia, as well as all imported and exported medical devices (per pack), whose turnover is performed in accordance with this law.

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

- 1) The name of the medical device, as well as the shape, strength and packaging of the medicinal product, if applicable;
- 2) A description of the medical device;

- 3) Name and address or seat of the manufacturer;
- 4) Name and address, or seat of the authorised representative of the manufacturer;
- 5) Amount of medical device;
- 6) The number of the decision on registration of a medical device, or the number of the decision authorising the import in accordance with Article 79 of this Law;
- 7) Number of lot or serial number of imported or exported or sold medical device;
- 8) Unique medical identification number (UDI) or bar code, if applicable;
- 9) The name of the legal or natural person, or the health institution for which the import is performed.

2) Collecting and processing data on Marketing and consumption of medical devices

Article 86

The wholesaler and the manufacturer or the authorised representative of the manufacturers shall, based on the records referred to in Article 85 of this Law, submit to the Agency a report on turnover and consumption in the previous calendar year, by April 15 of the current year at the latest.

The Agency shall collect and process data on the Marketing and consumption of medical devices referred to in paragraph 1 of this Article for one calendar year.

The report referred to in paragraph 1 of this Article shall be a business secret, and the processed data referred to in paragraph 2 of this Article shall be made available to the public.

8. Plan for urgent withdrawal of the medical device from the market

Article 87

The manufacturer, or an authorised representative of the manufacturer, as well as the wholesaler, shall have a plan for the urgent withdrawal of a medical device from the market, which will ensure the effective withdrawal of the medical device from the market at the request of the Ministry, manufacturer or authorised representative of the manufacturer.

9. Informing the Ministry

Article 88

Wholesale is obliged to inform the Ministry without delay on the following:

- 1) All significant changes in terms of personnel, space, or place of storage of medical devices and equipment, as well as entrusted tasks;
- 2) Any incident that could affect the quality of the medical device or safe handling;
- 3) Every problem in ensuring the continuous supply of the market with a medical device referred to in Article 81 of this Law.

In the cases referred to in paragraph 1 of this Article, the Ministry may suspend or prohibit the circulation of a medical device or order the withdrawal of a medical device from the market, or abolish the decision granting the licence for the wholesale distribution of medical devices in accordance with this Law.

10. Destruction of medical devices

Article 89

Medical devices and materials used in the procedure for the manufacture and trade of wholesale medical devices that have expired the deadline for use or for which a defect has been established with respect to the prescribed quality, as well as medical devices which are prohibited for Marketing, or which have been withdrawn under the conditions prescribed by this Law from the market, and which constitute waste, must be destroyed in accordance with the law governing waste management and the regulations adopted for its implementation.

The manufacturer, or an authorised representative of the manufacturer, wholesaler, as well as a legal or natural person who, in accordance with the law, performs retail trade of medical devices, is obliged to organise the destruction of medical devices in accordance with the law governing waste management and the regulations adopted for its implementation.

11. Retail trade of medical devices

1) Retailing

Article 90

Retail trade of medical devices is carried out in pharmacies and private practice that performs activities in accordance with the law.

Retail medical devices are also sold in specialised medical equipment shops in accordance with this Law and the regulations adopted for its implementation.

The Ministry shall issue a license for performing retail trade to a specialised shop referred to in paragraph 2 of this Article by the decision no later than 60 days from the date of receipt of the application for the issue of a licence submitted in writing.

If the request referred to in paragraph 3 of this Article is not complete, the Ministry shall notify the applicant in writing to submit the required data no later than 15 days from the date of receipt of the notification.

The time limit referred to in paragraph 3 of this Article shall cease to run from the date when the Ministry requests additional information from the applicant and continues to run from the date of submission of the requested information.

The licence referred to in paragraph 3 of this Article shall be issued for a period of five years.

The Minister's decision referred to in paragraph 3 of this Article is final in the administrative procedure and an administrative dispute can be initiated against it.

Certain types of medical devices may also be sold at other closed retail outlets in accordance with the regulations governing trade.

A manufacturer of custom manufactured medical devices manufactured by order (custom-made device) may issue a medical device without a marketing authorisation for medical devices issued by the Ministry.

The list of medical devices that can be sold in other places referred to in paragraph 8 of this Article shall be published on the official website of the Agency.

The register of specialised medical device shops in electronic form is established and maintained by the Chamber of Commerce of Serbia as an entrusted job.

At the request of a specialised shop or other legal or natural person with an undisputed legal interest, the Serbian Chamber of Commerce issues a certificate on the data kept in the register referred to in paragraph 11 of this Article.

The Minister shall prescribe which data shall be entered in the register referred to in paragraph 11 of this Article, as well as the method of entry.

The Minister shall prescribe the conditions, content of the request, as well as the manner of issuing, amending and updating the licence for the sale of medical devices in retail stores in specialised stores.

2) Amendments, supplements and renewal of the marketing authorisation for medical devices in specialised shops

Article 91

If the specialised shop changes or adds the conditions from the license for retail medical devices, it is obliged to submit to the Ministry in writing a request for modification or supplementation of the licence.

On the basis of verification of data from the request referred to in paragraph 1 of this Article, the Ministry shall issue a decision on amending or supplementing the licence for retail medical devices at the latest within 30 days from the date of receipt of the request.

If the request referred to in paragraph 1 of this Article is not complete, the Ministry shall notify the applicant in writing to submit the required data no later than 15 days from the date of receipt of the notification.

The time limit referred to in paragraph 2 of this Article shall cease to run from the date when the Ministry requests additional information from the applicant and continues to run from the date of submission of the requested information.

Prior to the expiration of the period for issuing a licence for retail medical devices, a specialised shop shall be obliged to submit to the Ministry in writing a request for renewal of the licence in accordance with this Law and the regulations adopted for its implementation.

On the basis of verification of data from the request referred to in paragraph 5 of this Article, the Ministry shall issue a decision on renewal of the licence for retail medical devices at the latest within 30 days from the date of receipt of the request.

If the request referred to in paragraph 5 of this Article is not complete, the Ministry shall notify the applicant in writing to submit the required data no later than 15 days from the date of receipt of the notification.

The time limit referred to in paragraph 6 of this Article shall cease to run from the date when the Ministry requests additional information from the applicant and continues to run from the date of submission of the requested information.

The decision of the Minister from paragraphs 2 and 6 of this Article is final in the administrative procedure and an administrative dispute can be initiated against it.

3) Retail conditions

Article 92

A medical device may be in retail if:

- 1) The conformity assessment has been carried out in accordance with this Law and the regulations adopted for its implementation;
- 2) Is registered in the Register of Medical Devices and manufactured by a legal or natural person registered in the Register of Manufacturers;
- 3) Is marked in accordance with this Law and the regulations adopted for its implementation;
- 4) The expiry date marked on the packaging has not passed and no non-compliance with the essential requirements has been established;
- 5) Retail medical equipment is carried out in accordance with this Law and the regulations adopted for its implementation.

XII LABELLING AND INSTRUCTIONS FOR USE OF THE MEDICAL DEVICE

1. Data specified by the manufacturer

Article 93

Every medical device on the market must be accompanied by information necessary for its safe and proper use, in relation to the training and knowledge of the potential user, as well as the data necessary for the identification of the manufacturer.

The information referred to in paragraph 1 of this Article shall be data indicating the medical device and the information in the instruction manual.

Where feasible and appropriate, information for the safe use of a medical device must be indicated on the medical device itself, or the packaging of each individual part or, where appropriate, on the sales package. If this is not feasible, on an individual package of each part, the information is given in the instruction manual used by one or more products.

The instructions for use must be in the package of each medical device. Exceptionally, the instruction manual is not required for medical devices of Class I or IIa if they can be used safely without the instructions for use. Exceptionally, in justified cases, the instruction manual is not required for in vitro diagnostic medical devices, if they can be used correctly and safely without the instructions for use.

In the case where exclusively healthcare professionals use the medical device and the accompanying equipment, or if their use is not foreseen by persons other than healthcare workers, the manufacturer may provide instructions for use in electronic form instead of in paper form.

In the case where the instructions for use in electronic form replace the instruction for use in written form, the manufacturer must, before placing that medical device on the market, carry out a risk assessment and ensure that the manual for use in electronic form does not pose a risk to public health.

The instructions for the use of the medical device must be written in Serbian and must be in full compliance with the original text of the manufacturer's instructions.

The Minister shall prescribe the contents and manner of marking of the external and internal packaging of a medical device, as well as the content of the instructions for the use of a medical device.

Article 94

The labelling of the medical device must contain detailed information in accordance with this Law and the regulations adopted for its implementation.

If the purpose of the medical device is not obvious to the user, the manufacturer must clearly state it on the package of the medical device and in the instructions for use.

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

The outer and inner packaging of the medical device for professional use must be marked in Serbian or English, and for medical devices that the patient uses on their own, it must be marked in Serbian.

Information on the manufacturer's authorised representative and the number of medical device registration solutions may be indicated on the sticker.

Article 95

The instructions for use, if necessary, must contain the detailed information prescribed by this Law and the regulations adopted for its implementation.

If the medical device is delivered with the intention of sterilising it before use, the instructions for cleaning and sterilisation must be such that, if properly followed, the medical device continues to comply with the essential requirements.

If a medical device carries the mark of single-use, information is provided on its known characteristics and technical factors known to the manufacturer that might pose a risk if the medical device is reused. If it is not necessary in accordance with this Law and the regulations adopted for its implementation, the information should be available at the request of the user.

The instructions for use must contain detailed information prescribed by this Law and the regulations adopted for its implementation, which enable healthcare professionals to inform the patient of all contraindications and precautions.

If the conformity assessment body has approved the labelling of the medical device with a sign of compliance, the outer and inner packaging of the medical device must, in addition to the sign of conformity, also have the identification number of that body.

The outer and inner packaging of a Class I medical device, as well as the classes of other in vitro diagnostic medical devices, for which the manufacturer places the mark of conformity, are marked only with the sign of conformity.

Article 96

The medical device may also be used for indications, dosages, method of administration or age of the patient not listed in the labelling or instruction for the use of a medical device (hereinafter: off-label application).

The specialist doctor of the appropriate branch of medicine prescribes a medical device for the application of an off-label and provides for the fulfilment of the following conditions:

- 1) The ethical board of the healthcare institution in which the patient is treated is given the opinion that the use of a medical device is necessary, that all other therapeutic possibilities 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) Based on expert and scientific knowledge, they concluded that the medical device is safe and appropriate for the patient;
- 3) Possess sufficient evidence based on the experience of the safety and performance of the medical device for that medical indication;
- 4) Assumes responsibility for prescribing a medical device and monitoring the patient's treatment;
- 5) Keep clear, precise and accurate records of off-label medical devices in the medical records of the patient with stated medical reasons for prescribing that medical device, in accordance with the law.

XIII MEDICAL DEVICE ON THE MARKET

1. Surveillance of the medical device on the market

Article 97

Surveillance of the medical device on the market includes post market surveillance and market surveillance.

The manufacturer, or the authorised representative of the manufacturer, is obliged to continuously monitor the medical device on the market in order to identify any need to immediately apply all necessary corrective or preventive measures. About the implemented corrective and preventive measures, the manufacturer, or the authorised representative of the manufacturer keeps a record and is obliged to report to the Agency.

The Agency provides, organises and coordinates the collection and analysis of data obtained after placing a medical device on the market.

The Agency may require the manufacturer, or the authorised representative of the manufacturer, to submit a reasoned and evidence-based report on the experience of a medical device on the market.

The Minister shall prescribe more precisely the conditions and manner of monitoring of the medical device on the market.

2. Data on incidents after placing the medical device on the market - Vigilance system

Article 98

The Agency records, evaluates and undertakes measures within its jurisdiction in the event of an incident of a medical device, as follows:

- 1) Any malfunction or alteration of the characteristics or performance of the medical device, as well as the irregularities in the marking or the instructions for use which have led or could have led to the death of the patient or user or to a serious deterioration of their health condition;
- 2) Any technical or medical reason related to the performance of a medical device referred to in item 1) of this paragraph, which is the reason for the manufacturer or the authorised representative of the manufacturer to withdraw from the market a medical device of the same type.

The incident referred to in paragraph 1 of this Article, a healthcare worker or a healthcare institution or coordinator for vigilance, is obliged to notify the Agency and the manufacturer or the authorised representative of the manufacturer.

The Agency shall notify the Ministry of the incident referred to in paragraph 1 of this Article and propose appropriate measures in accordance with this Law and the regulations adopted for its implementation.

Article 99

The Agency supervises the investigation of the incident by the manufacturer or the authorised representative of the manufacturer and undertakes the measures necessary to amend or supplement the measures taken by the manufacturer or the authorised representative of the manufacturer. Depending on the results of the survey, the Agency provides all the information needed to prevent incidents or to limit their consequences after the placing of medical devices on the market and into service (hereinafter: the vigilance system).

Health institutions, as well as private practice, healthcare workers, manufacturers, or an authorised representative of manufacturers and wholesalers, as well as persons involved in the distribution, delivery or putting into service of a medical device, are obliged to notify the Agency without delay of any incident. This duty also applies to persons responsible for the calibration and maintenance of a medical device.

The healthcare institution is obliged to appoint and report to the Agency for the coordinator for vigilance.

The manufacturer or the authorised representative of the manufacturer is obliged to submit to the notified body, i.e. the designated body that performed the conformity assessment, information on

any changes made in the system of vigilance, in case these changes influence the compliance of the medical device.

The designated body is involved in the system of vigilance in the area of evaluation of procedures and verification of implementation of procedures of vigilance, connection with other systems (Corrective and Preventive Action - CAPA), assessment of the impact of vigilance on issued certificates of conformity and it is obliged to carry out certain research, or repeat the evaluation of compliance of the procedures of vigilance at the request of the Ministry, and at the proposal of the Agency.

The Agency processes, selects and maintains a database on medical device incidents.

Data and information on the undertaken and implemented measures related to incidents of the medical device shall be published on the Agency's website.

The Minister prescribes closer conditions and the manner of implementation of the system of vigilance.

Article 100

In order to eliminate the danger to the health and safety of patients and other users of a medical device, the Agency provides, organises and coordinates the collection of data, analysis and assessment of the risk of using a medical device, in particular with regard to reporting incidents.

The Agency shall inform the Ministry of the results of the assessment and the undertaken measures regarding the incidents of the medical device, which resulted in the taking of certain measures.

The personal data of the patient, user or other person may be submitted to the Agency or the Ministry, if necessary for fulfilling the obligations referred to in paragraph 1 of this Article in accordance with the law governing the protection of personal data.

In order to ensure the vigilance system, the Agency cooperates with the competent authorities of the member states "EEA" and the European Commission, as well as with "EUDAMED", "CAMD", the World Health Organization, competent authorities of other states responsible for public health or occupational diseases, notified and named bodies, health insurance funds, professional associations, as well as other bodies that have risk data associated with a medical device.

The manufacturer, or the authorized representative of the manufacturer, is obliged to notify the Agency without delay of the initiated Safety-corrective measure on the ground (FSCA).

3. Technical assessment of the medical device on the market

Article 101

The technical evaluation of the medical device on the market is carried out:

- 1) By investigating, or controlling samples of medical devices taken by the random selection method from the market (hereinafter: systematic control);
- 2) By investigating, or controlling, a sample of a medical device in case of a declaration of quality defect, as well as a medical device suspected of being falsified (hereinafter: extraordinary control).

Systematic control of medical devices is carried out on the basis of the annual plan for systematic control of medical devices on the market, prepared by the Ministry and the Agency, based on risk analysis, probability of occurrence of harmful consequences, data on vigilance, data obtained in the framework of monitoring of the medical device on the market and other data.

Systematic control includes the conformity assessment of the marking of the medical device.

Extraordinary control is carried out at the request of the Ministry in order to solve the problems identified (notification of suspicion of a defect of the quality of the medical device, or suspicion that the medical device has been forged). In case of suspicion about the non-conformity of the medical device with the essential safety requirements, sampling of this medical device is carried out and the examination or assessment of conformity.

The Agency or an authorised body according to the regulations of a valid national or European pharmacopoeia or an international pharmacopoeia may perform the technical evaluation of the medical device on the market, by conducting physical, chemical, biological and microbiological tests.

In the procedure of laboratory control of the medical device referred to in paragraph 5 of this Article, the Agency may require the manufacturer or the authorised representative of the manufacturer to provide, within 30 days, the necessary quantity of samples, analytical methods and reference or labour standards necessary for conducting the analytical procedure of the manufacturer.

For the tests referred to in paragraph 1 of this Article, the manufacturer or the authorised representative of the manufacturer shall, at the request of the Ministry, submit evidence of the technical assessment carried out by the Agency or an authorised body, that is, an accredited laboratory of the EEA or a state with which the European Commission has concluded a contract mutual recognition of conformity assessment procedures in cases where there is no authorised body in the Republic of Serbia with the scope of accreditation covering the necessary examinations referred to in paragraph 1 of this Article.

If the authorised body or the Agency determines non-compliance with the essential requirements, i.e. defects in the quality of a medical device, they are obliged to notify the Ministry without delay.

Article 102

Upon the technical evaluation referred to in Article 101 of this Law, the Agency or the authorised body shall issue a certificate of analysis, i.e. a certificate on the technical assessment carried out no later than 30 days after the submission of the complete request.

The Minister shall prescribe the method of technical assessment of the medical device on the market, the types of quality defects and the manner of treatment in case of deviation from the essential requirements, or the defect of the quality of the medical device, as well as the manner of issuing and the content of the certificate of analysis referred to in paragraph 1 of this Article.

XIV PROCEDURE FOR PROTECTION AGAINST THREAT TO PUBLIC HEALTH

Article 103

The Agency and the Ministry shall take all necessary measures to protect public health and safety of patients, users and other persons, including health workers from the risks that a medical device may cause.

In order to protect public health, the Ministry may prohibit the production or circulation of a medical device.

If the Ministry estimates that a medical device constitutes an unacceptable risk to public health or the safety of patients, users or other persons, or in other aspects of public health protection, and if it does not meet the requirements prescribed by this Law and the regulations adopted for its implementation, it shall, without delay, order the manufacturer, or the authorised representative of the manufacturer, to take all appropriate and justified preventive or corrective measures, to prohibit or restrict the placing of a medical device on the market, to set specific requirements for the placement of a medical device on the market, to order the withdrawal or withdrawal of a medical device within a reasonable period of time from the market, and in proportion to the nature of the risk or non-compliance with the provisions of this Law and the regulations adopted for its implementation. The Ministry may take all other necessary and justified measures in accordance with the law.

If the Agency determines that a custom-made device, although properly installed, maintained and used in accordance with the intended use, can compromise the health and safety of patients, users or other persons, or their property, the Agency shall propose to the Ministry to suspend, prohibit the circulation or use of a medical device, or order the withdrawal of a medical device from the market.

The Agency shall inform all persons who may be exposed to danger from a medical device in a timely and appropriate manner.

The official public warning, in addition to the information on the official website of the Agency, is given only in the event of an emerging danger when other equally effective measures cannot be taken or cannot be undertaken in a timely manner.

XV ADVERTISING THE MEDICAL DEVICE

1. The form of advertising

Article 104

Advertising of a medical device is any form of providing truthful information about a medical device to the general and professional public in order to encourage the prescribing and supply of medical devices, their sale and consumption from the manufacturer, or an authorised representative of the manufacturer, as well as from a legal or physical person who carries out the sale of medical devices (hereinafter: the advertiser of a medical device).

Advertising of a medical device within the meaning of this Law shall be considered:

- 1) Advertising the medical device to the general public;
- 2) Advertising the medical device to the expert public.

The general public, in terms of this law, are citizens of the Republic of Serbia.

The professional public, within the meaning of this law, are medical workers who prescribe or use medical devices, professionals in the production and trade of medical devices in retail and wholesale, as well as in the organisation of compulsory health insurance.

Information advertised on a medical device must be truthful and scientifically proven and professional and the general public must not be misled.

The information referred to in paragraph 5 of this Article shall be given for the proper and rational use of a medical device with respect to ethical standards.

The advertising of a medical device must comply with this Law and the regulations adopted for its implementation, the essential requirements, as well as the instructions for using the medical device from the manufacturer.

The Minister shall prescribe the conditions and manner of advertising of the medical device referred to in paragraph 1 of this Article.

Article 105

Advertising of medical devices includes:

- 1) Advertising medical devices through means of public information, 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 medical workers who prescribe medical devices, or who use medical devices by informing them at expert meetings, 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 is involved (payment of travel, accommodation, food expenses, as well as the cost of compulsory participation in scientific and promotional meetings).

Article 106

Advertising of a medical device within the meaning of this Law shall not be considered:

- 1) Giving advertisers an answer to specific questions regarding a particular medical device, provided that the responses do not have a promotional character;
- 2) Providing information relating to the illness or state of human health, provided that the name of the medical device is not indirectly mentioned;
- 3) The provision of copies of scientific articles published in medical and pharmaceutical journals by advertisers to healthcare professionals who prescribe and use medical devices to professionals in the field of wholesale and retail medical supplies, provided that the scientific articles submitted are complete (in their original form), that is, that only positive information on the medical device is not included and that they do not contain any additional advertiser comments;
- 4) Only specifying the name of the medical device, the description of the medical device, or the trademark if it serves solely as a reminder;
- 5) Marking a medical device in accordance with this Law and the regulations adopted for its implementation;
- 6) Objective information on the medical device of the general public and the professional public in health magazines or health sections of other journals, as well as in other means of public information, which does not indicate the wrong conclusion and which aims to provide answers to specific questions in relation to a certain medical device, provided that the information on the medical device is in accordance with the instructions for use of the medical device, using only the description of the medical device, provided that the notification has no advertising elements;
- 7) Providing information about a medical device that relates to a change in packaging, an adverse reaction to a medical device, a sales catalogue of a medical device with a price intended for the professional public, provided they do not contain advertising elements;
- 8) Objectively informing at international conferences held in the Republic of Serbia about a medical device that is not registered in the Republic of Serbia, but which is on the market of the EU Member States, that is harmonised with the European Union regulations concerning medical devices, with the notification that there are no advertising elements.

2. Comparative promotion of the medical device

Article 107

The advertiser of the medical device can independently promote the medical device or with another, or through another legal or natural person, which they determine by engaging the

employed persons in that person (hereinafter: comparative promotion of a medical device), in accordance with this Law and bylaws adopted for its implementation.

3. Advertising of the medical device to the general public

1) The mode of advertising to the general public

Article 108

Advertising of the medical device to the general public includes the advertising of a medical device intended for use by a patient whose advertising is not prohibited by law through public information media, the Internet, advertising in public places, and other forms of advertising to the general public (delivery of advertising material by mail, visits etc.).

The advertising message for a medical device whose advertising is allowed must contain clear information that the product being advertised is a medical device and must not be misled.

Advertising of a medical device to the general public cannot be done contrary to the provisions of this Law and the bylaws adopted for its implementation.

2) Advertising to the general public

Article 109

When advertising a medical device, the general public cannot be led to the impression that:

- 1) The medical device has no adverse reaction;
- 2) There is no need to consult a physician prior to the application of the medical device;
- 3) A medical examination, advice or surgical intervention may be avoided by the use of the medical device;
- 4) The application of the medical device guarantees success in the treatment of the disease;
- 5) A particular medical device is best, or better than other medical devices;
- 6) It is good to take and administer the medical device even when there are no signs of illness, that is, it improves health;
- 7) The health of a person who does not use the medical device will be violated, except in the case of a campaign conducted by the Ministry (prevention of epidemics) in accordance with the law;
- 8) Medical device means food, cosmetics or other objects of general use;
- 9) The medical device is entered in the Register of Medical Devices, or that in the following period the medical device will be registered in the Register;
- 10) The recommended medical device may be replaced by another medical device;
- 11) Because of its natural origin, the medical device is harmless and effective.

Article 110

When advertising a medical device to the general public, the following cannot be presented:

- 1) Claims that the medical device will be included in the list of medical devices that are prescribed and issued at the expense of compulsory health insurance or voluntary health insurance, except in the case of a campaign conducted by the Ministry (e.g. prevention of epidemics);
- 2) Claims regarding the price of a medical device, as well as the part of the price of a medical device that is provided from the means of compulsory or voluntary health insurance;
- 3) Recommendations of health or scientific workers about the performance, or characteristics of a medical device that encourages the use of a medical device;
- 4) Recommendations of a person who, due to their popularity, could influence the use of a medical device, that is, use of the image of that person in the advertising of a medical device.

Article 111

When advertising a medical device to the general public, the following cannot be used:

- 1) History of the disease or presentation of diagnostic procedures which could lead to wrong self-diagnosis or self-diagnosis;
- 2) Inappropriate, disturbing or misleading expressions and images of changes in the human body caused by a disease, injuries or the effects of a medical device on the human body or parts of the body.

In the advertising of a medical device to the general public, children who receive a medical device cannot be shown, that is, they cannot be shown as having access to a medical device without the presence of adults.

The advertising of a medical device to the general public must not be exclusively or mainly directed at children.

The advertising of a medical device to the general public cannot include the name of a pharmacy, private practice, specialised shops and wholesale venues at which a medical device can be purchased.

In the advertising of a medical device to the general public, claims or conclusions cannot be made about the effectiveness of a medical device that is the subject of clinical trials in the Republic of Serbia or abroad.

When advertising a medical device to the general public, personal data on the illness or condition of a particular person or group of persons, diagnoses, therapeutic procedures that have been used in the treatment procedure, and the medical device used in the treatment of a particular person or group of persons cannot be collected and presented.

It is not possible to give free samples of a medical device to the general public. Free samples of only that medical device that can be sold in places other than in pharmacies and specialised

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.

Advertising of medical devices that are issued at the expense of compulsory health insurance cannot be carried out.

In addition to the medical devices referred to in paragraph 8 of this Article, in order to protect public health, the Minister may prescribe other medical devices which cannot be advertised.

4. Promote the medical device to the professional public

1) Promoting to the professional public

Article 112

Promoting a medical device to the expert public must contain basic information about a medical device.

The data referred to in paragraph 1 of this Article must be accurate, updated, verifiable and sufficiently complete that the recipient can form their opinion on a particular medical device based on them, as well as have the date of creation and last revision.

Advertising materials intended for the professional public must be labelled “solely for the professional public”.

The advertiser promotes the medical device by acquainting the expert public with the performance or characteristics of the medical device, in order for the expert public to obtain a position on the medical device.

The material used for the promotion of a medical device must include data on the date of registration of the medical device, allegations, tables or other data taken from medical journals or other scientific papers and which must be updated, relevant and faithfully transferred with the guidance of the literature and the correct source of information.

In the promotional material referred to in paragraph 5 of this Article, the word “safe” must not be used to describe the medical device without the appropriate explanation, in accordance with the essential requirements.

Access to professional information through advertising and information to the expert public on a medical device in a written, visual, audio, electronic or any other form must be limited to the professional public referred to in Article 104, paragraph 4 of this Law.

Promoting the medical device to the expert public is done by professional associates of advertisers.

Professional associates of advertisers promoting the medical device shall be obliged to transmit to the advertiser all information regarding adverse reactions to the medical device, which they have received in the process of promoting the medical device.

Professional associates of advertisers who promote the medical device can only give to professionals from the professional public items that do not have higher value, that is, their value is symbolic and which are related to the medical, dental or pharmaceutical practice or activity of the employer with whom the professional public is employed (e.g. pencil, notes, calendar and other similar items of small value), which in terms of the law is not considered advertising.

5. Advertising terms

Article 116

Only a medical device that complies with the essential requirements, or which is registered, is advertised.

The medical device cannot be advertised by misleading or describing the illness or the success of the treatment, so it implies self-regulation, or in an inappropriate and sensationalist manner about the success of the medical device in the treatment by displaying images, etc.

XVI MEDICAL DEVICES FOR DUAL USE

Article 117

Medical devices intended for use in veterinary medicine in accordance with the law, can only be used in veterinary medicine, or they cannot be used in human medicine.

A dual use medical device, or intended by the manufacturer for use in both human and veterinary medicine, cannot be marketed and used in human medicine if it is not compliant with the essential requirements.

XVII SUPERVISION IN THE FIELD OF MEDICAL DEVICES

1. Execution of inspection supervision

Article 118

Supervision of the implementation of this Law and the regulations adopted for its implementation is carried out by the Ministry through an inspector for medical devices (hereinafter: inspector).

Supervision of the performance of affairs entrusted by this Law shall be performed by the Ministry.

In performing the supervision referred to in paragraph 1 of this Article, the inspector is authorised to:

- 1) Determine and control the implementation of the Good Practice Guidelines in the distribution;
- 2) Determine and control the fulfilment of the conditions for production, that is, the production of a medical device in accordance with this Law, the wholesale distribution of medical devices, the retail sale of medical devices in specialised shops in terms of space, equipment, personnel and other conditions prescribed by this Law and the adopted regulations for the implementation of this law;
- 3) Check whether the medical device on the market has the necessary supporting documentation (identification and compliance document);
- 4) Perform a check of the conditions for carrying out conformity assessment activities with the designated or authorised body;
- 5) Prohibit the legal or natural person from producing, or making medical devices, the sale of medical devices, if they do not meet the conditions prescribed by this Law and the regulations adopted for its implementation;
- 6) Order a legal or natural person to harmonise business, or to correct the deficiencies in terms of the conditions prescribed by this Law and the regulations adopted for its implementation, within a period which cannot be shorter than 15 days nor longer than six months from the date of receipt of the decision by which this measure is required;
- 7) Order the designated or authorised body to remedy the deficiencies in terms of the conditions prescribed by this Law and the regulations adopted for its implementation, within a period that cannot be shorter than 15 days nor longer than 60 days from the date of receipt of the decision by which this measure is required;
- 8) For the purposes of systematic or extraordinary control, instruct the manufacturer, or authorised representative of the manufacturer, to carry out the assessment of conformity, or the examination of a medical device;
- 9) The legal or natural person referred to in item 6 of this paragraph prohibits the production or the development of medical devices, the wholesale distribution of medical devices and the retail sale of medical devices, if it fails to reconcile the business or removes the defects within the deadline referred to in item 6) of this paragraph;
- 10) Prohibit a legal entity or a natural person from circulating a medical device if it does not fulfil the conditions prescribed by this Law and the regulations adopted for its implementation;
- 11) Limit or suspend the placing on the market or the use of a medical device or its series that do not meet the requirements prescribed by this Law and the regulations adopted for its implementation;
- 12) Order the withdrawal of a medical device or its series from the market in cases provided for by this Law and the regulations adopted for its implementation;
- 13) Order the destruction of a medical device that does not comply with the essential requirements, in accordance with this Law and the regulations adopted for its implementation;
- 14) Suspend or ban the conducting of a clinical trial if it is conducted contrary to this Law and the regulations adopted for its implementation, at the proposal of the Agency, or ex officio;

- 15) Prohibit the advertising of medical devices that is contrary to the conditions prescribed by this Law and the regulations adopted for its implementation by all legal or natural persons participating in the procedure of advertising medical devices, and that, on the basis of data provided by the Agency to the Ministry in accordance with this Law, order the prohibition of advertising or the use of materials used in the process of advertising medical devices and other documentation relating to the advertising of medical devices;
- 16) Inspect the documentation and records of the manufacturer, or the authorised representative of the manufacturer, of all reported and received data on vigilance, as well as the applications submitted to the Agency and health institutions;
- 17) Take other prescribed measures, in accordance with the law.

2. Inspector

1) Conditions for the work of the inspector

Article 119

The work of the inspector for medical devices can be performed by a person who has completed a medical, dental, pharmaceutical, technological, electro-technical, mechanical or chemistry faculty, passed the state professional examination and exam for inspectors in accordance with the law regulating inspection supervision.

The law regulating the general administrative procedure, the law governing civil servants and the law on inspection supervision shall apply to the exclusion of inspectors from participation in procedures conducted before an inspectorate.

2) Inspector's legitimacy

Article 120

The inspector has a special identity card, which they identify and which they are obliged to show at the request of the responsible or other interested person, during the supervision.

The form and content of the identity card referred to in paragraph 1 of this Article shall be prescribed by the Minister.

3) Authorisation of the inspector

Article 121

The inspector is autonomous within the limits of the powers determined by this Law and a regulation adopted for its implementation, and is personally responsible for their own work.

In performing the supervision referred to in Article 118 of this Law, the inspector is authorised to:

- 1) Review general and individual acts, records and other documentation related to the production, that is, the production of a medical device, the Marketing, advertising, testing and technical evaluation of the medical device, clinical examination, vigilance, as well as the documentation related to the assessment of conformity;
- 2) Hear and take statements from responsible and interested persons;
- 3) Inspect business premises, facilities, plants, devices, equipment, as well as documentation on the prescribed personnel related to the production of medical devices, Marketing, testing and technical evaluation of medical devices, or assessment of conformity;
- 4) Have immediate insight into the implementation of Good Distribution Practices, as well as standard and operational procedures in these areas;
- 5) Take samples of medical devices from the market, or production for the purpose of determining quality;
- 6) Take copies of the reviewed documents that are subject to supervision, as well as to obtain evidence on the established factual situation by photographing objects, production space, equipment, etc.;
- 7) Undertake other measures and actions related to the subject of supervision, in accordance with this Law.

4) Minutes and the decision on performed inspection

Article 122

The inspector shall be obliged to draw up a record containing the findings of the state on each performed inspection and actions undertaken in the supervision procedure.

The minutes referred to in paragraph 1 of this Article shall be obligatory delivered to the subject under supervision, within eight days from the end of the inspection.

The supervised entity has the right to make written observations on the inspection supervision report, within five working days of its receipt.

The inspector assesses the objections all together, each separately and in relation to each other.

The Inspector may execute additional inspection to determine the facts to which the remarks relate.

If new facts and new evidence are made in remarks on the record, due to which the factual situation determined in the minutes or other legal and other assessments needs to be changed, the inspector shall compile a supplement to the minutes, to which no objection can be made.

Based on the minutes, the inspector issues a decision ordering the subjects under supervision to carry out measures and actions.

An appeal against the decision referred to in paragraph 7 of this Article may be appealed to the Minister.

The minister's decision referred to in paragraph 8 of this Article is final in the administrative procedure and an administrative dispute can be initiated against it.

Based on the minutes made by the inspector on the conditions for the production, manufacture, marketing of medical devices, the Minister shall issue a decision.

The minister's decision referred to in paragraph 10 of this Article is final in the administrative procedure and an administrative dispute can be initiated against it.

If the inspector estimates that the criminal offence, the commercial offence or the misdemeanour committed by the conduct or the non-acceptance of the subjects for which the supervision was carried out, they are obliged to submit to the competent authority without delay a report for the committed criminal act or commercial offence, or the request for the initiation of the misdemeanour procedure.

3. The duties of the person subject to inspection supervision

Article 123

Legal entities and individuals whose business is subject to the supervision of the Ministry are obliged to enable the inspector to have unhindered access and carry out supervision in accordance with this Law, regardless of whether it is an announced or unannounced supervision, and that it is sufficient to provide them without compensation a sufficient number of samples of the medical device for analysis, or to provide them with all the necessary information at their disposal.

The costs of taking samples of medical devices are borne by the manufacturer, or an authorised representative of the manufacturer, healthcare institution, private practice, wholesale, pharmacy or a specialised shop of medical devices.

The inspector shall be obliged to act in accordance with this law, the regulations adopted for its implementation and the law regulating inspection supervision, conscientiously and impartially, or to keep as a business secret the data that occur during the execution of supervision.

Article 124

The manufacturer or authorised representative of the manufacturer, persons with headquarters in the Republic of Serbia who carry out marketing, clinical examination, performance assessment tests, packaging, placing on the market, or in whose business premises sterilisation or finishing of medical devices is performed, exposure, installation and use of medical devices, as well as persons referred to in Article 125 of this Law shall be subject to supervision by the Ministry.

The Ministry shall take the necessary measures to eliminate the identified deficiencies in terms of the conditions prescribed by this Law and the regulations adopted for its implementation and

taking into account the potential risk, check whether the conditions for placing on the market, installation, functioning and use of the medical device have been fulfilled.

If there is sufficient evidence of marking a medical device with a sign of compliance contrary to this law or the risk that a medical device causes, the Ministry may, ex officio or at the proposal of the Agency, instruct the manufacturer or the authorised representative of the manufacturer to carry out further tests of the medical device.

The Ministry may, ex officio or at the proposal of the Agency, order the person referred to in paragraph 1 of this Article to remedy the defects established in the procedure for supervision of production, manufacture, trade, clinical examination, performance assessment and sterilisation or finishing and full restoration of medical devices.

Legal entities and natural persons referred to in paragraph 1 of this Article whose work is subject to supervision shall be obliged to enable the inspector to have unhindered access and supervision in accordance with this Law, as well as access to all necessary information and documentation, to provide the necessary tests and make accessible staff and assistance during inspection supervision.

4. Cases in which the obligations and responsibilities of the manufacturer of a medical device apply to importers, wholesalers and other persons

Article 125

Obligations and responsibilities of the manufacturer, or authorised representative of the manufacturer of the medical device prescribed by this Law, shall also apply to importers, wholesalers and other legal and natural persons who:

- 1) Make available on the market a medical device under its own name, registered commercial name or registered trademark;
- 2) Change the intended purpose of a medical device that has been placed on the market, or in use;
- 3) Modify a medicinal product that has been placed on the market, or in use in such a way that it may affect its compliance with the essential requirements.

The provisions of paragraph 1 of this Article shall not apply to a person who is not a manufacturer, and which compiles or adjusts the medical device put on the market to an individual patient.

For the purposes of paragraph 1, item 3) of this Article, the modification of a medical device that may affect its compliance with the essential requirements shall not be considered:

- 1) Marking the medical device with the label, providing instruction for use, or translation of instructions for use in the Serbian language of a medical device that is placed on the

market and other information provided by the manufacturer required for trade in the Republic of Serbia;

- 2) The change of the outer packaging of a medical device that has been placed on the market, including the size of the package, if repackaging is necessary for the marketing of a medical device on the market of the Republic of Serbia and if it is carried out under conditions that do not affect the original requirements of the medical device. In the case of a sterile medical device, it is presumed that there has been an adverse effect on the original requirements of the medical device if the package providing the sterile conditions is open, damaged, or otherwise negatively affected by the repackaging process.

Obligations and responsibilities of the manufacturer of medical devices applied to importers, wholesalers and other persons shall be prescribed by the Minister.

XVIII PENALTY PROVISIONS

1. Commercial offences

Article 126

A fine in the amount of RSD 1,500,000 to 3,000,000 shall be imposed on a legal entity for a commercial offence if said legal entity:

- 1) Does not carry out the assessment of conformity in the manner prescribed by this Law (Article 15 paragraphs 1, 3, 4, 5 and 6, Article 17 paragraph 2, Article 20 paragraphs 1 and 3, Article 25 paragraph 2, Article 27, paragraph 9, Article 79, paragraph 2 and Article 125);
- 2) Performs production, manufacture or trade of a medical device contrary to this Law (Article 12, Article 17, paragraph 1, Article 19 paragraph 1, Article 22, paragraphs 1 and 3, Article 25, paragraphs 1, 3 and 5, Article 34, paragraph 1, Article 36, paragraphs 1 and 2, Article 51, Article 52, paragraphs 3 and 4, Article 53, paragraphs 1, 2, 9 and 10, Article 54 paragraphs 1 and 8, Article 56, paragraph 3, Article 57, paragraph 1, Article 58, Article 60, paragraph 6, Article 61, paragraphs 1 and 5, Article 63, paragraph 4, Article 65, Article 67, Article 68, paragraphs 1, 3 and 4, Article 69, paragraphs 3 and 4, Article 70, paragraphs 1, 4 and 5, Article 71, paragraphs 1, 4, 5, 6. and 8, Article 75 paragraphs 1 and 5, Article 80, Article 81, Article 82, Article 83, paragraphs 1, 2, and 5 to 7, Article 84, paragraphs 4 to 6, Article 85, Article 86, paragraph 2, Article 87, Article 88, paragraph 1, Article 89, Article 90 t. 1 and 2, Article 91., 1 and 5, Article 92, Section 97, Paragraph 2, Article 101, paragraph 7, Articles 117 and 125);
- 3) Present a medical device at a business fair, exhibition, presentation, etc. contrary to the provisions of Article 19, paragraph 2 of this Law;
- 4) Mark the medical device in contravention of this Law (Article 18, Article 19, paragraphs 3 and 4, Article 25, paragraph 4, Articles 35, 93, 94, 95, 114 and 125);
- 5) Conduct a clinical trial contrary to this Law (Article 29 paragraphs 1, 2 and 4, Article 30 paragraph 2, Article 31, Article 32, paragraphs 1, 3 and 4, Article 33, Article 37. paragraphs 4 and 5, Article 41, paragraphs 1, 2 and 7, Article 42, paragraph 2, Article 43, paragraph 1, Article 44, paragraphs 1 and 5, Article 47, paragraph 3, Article 48 and Article 49, paragraphs 1 and 3);

- 6) Does not carry out vigilance in accordance with Article 54, paragraph 6, Article 97, paragraph 2, Article 99, 2, 3 and 4 and Article 100, paragraph 5 of this Law;
- 7) Advertise a medical device contrary to the provisions of this law (Article 104, paragraphs 5, 6 and 7, Article 108, paragraphs 2 and 3, Articles 109, 110, 111, 112, 113, 114, 115 paragraphs 2 to 8 and Article 116).

For the commercial offence referred to in paragraph 1 of this Article, a responsible person in a legal entity shall also be fined with a fine of RSD 100,000 to 200,000.

A fine in the amount of RSD 100,000 to 200,000 shall be imposed on a person responsible for documentation at the legal entity which is the manufacturer or authorised representative of the manufacturer if they act contrary to the provisions of Article 51, paragraph 4, Article 53, paragraph 1, Article 54, paragraph 1 and Article 56 paragraph 3 of this Law.

A fine of between RSD 100,000 and 200,000 shall be imposed on a person responsible for the manufacture and quality of a medical device in a legal entity if they act contrary to the provisions of Article 12, Article 17, paragraph 1, Article 19, paragraph 1, Article 22, 1 and 3, Article 25 paragraphs 1, 3 and 5, Article 34 paragraph 1, Article 36 paragraphs 1 and 2, Article 51, Article 57, Paragraph 1, Article 58, Article 60, Paragraph 6, Article 61, Paragraph 1 and 5, Article 65, paragraph 1, and Article 67 of this Law.

A fine of RSD 100,000 to 200,000 shall be imposed on a person responsible for the marketing of medical devices in a legal entity for a commercial offence if they act contrary to the provisions of Article 52, 3 and 4, Article 69, paragraphs 3 and 4, Article 70, paragraphs 1 and 5, Article 71, paragraph 1, Articles 80, 81 and 82, Article 83, paragraphs 1, 2, 5, 6 and 7, Article 84, paragraphs 4 to 6, Article 85, Article 86, paragraph 2, Articles 87, 88, paragraphs 1, 89 and 92 of this Law.

A fine of RSD 100,000 to 200,000 shall be imposed on a person responsible for vigilance in the legal entity which is the manufacturer or authorised representative of the manufacturer if they act contrary to the provisions of Article 54, paragraph 6, Article 97, paragraph 2, 2 and 4 and Article 100, paragraph 5 of this Law.

A legal entity who performs an activity or performs the activity referred to in paragraph 1 of this Article shall be given a fine of RSD 100,000 to 150,000 for a commercial offence referred to in paragraph 1 of this Article as an unregistered entity.

A fine of RSD 2,000,000 to 3,000,000 shall be imposed for a commercial offence on a designated or authorised conformity assessment body, if the conformity assessment procedure does not comply with Article 26, paragraph 2, Article 27, paragraph 2 to 6, Article 99, paragraph 5, and Article 101, paragraph 8 of this Law.

A fine in the amount of RSD 100,000 to 200,000 shall be imposed on a responsible person in a designated, or authorised conformity assessment body, for a commercial offence referred to in paragraph 6 of this Article.

Article 127

With the penalty referred to in Article 126 of this Law, a protective measure may also be imposed on a legal entity for the prohibition of performing certain economic activity from three years to ten years.

With the penalty referred to in Article 126 of this Law, a protective measure of confiscation of objects used or intended for the committing of a commercial offence or caused by the committing of a commercial offence shall be imposed on a legal entity.

2. Offences

Article 128

A fine of RSD 300,000 to 500,000 shall be imposed on an entrepreneur if they:

- 1) Do not carry out the assessment of conformity in the manner prescribed by this Law (Article 15 paragraphs 1, 3, 4, 5 and 6, Article 17 paragraph 2, Article 20 paragraphs 1 and 3, Article 25 paragraph 2, Article 27, paragraph 9, Article 79, paragraph 2 and Article 125);
- 2) Perform production, manufacture or trade of a medical device contrary to this Law (Article 12, Article 17, paragraph 1, Article 19 paragraph 1, Article 22, paragraphs 1 and 3, Article 25, paragraphs 1, 3 and 5, Article 34, paragraph 1, Article 36, paragraphs 1 and 2, Article 51, Article 52, paragraphs 3 and 4, Article 53, paragraphs 1, 2, 9 and 10, Article 54 paragraphs 1 and 8, Article 56, paragraph 3, Article 57, paragraph 1, Article 58, Article 60, paragraph 6, Article 61, paragraphs 1 and 5, Article 63, paragraph 4, Article 65, Article 67, Article 68, paragraphs 1, 3 and 4, Article 69, paragraphs 3 and 4, Article 70, paragraphs 1, 4 and 5, Article 71, paragraphs 1, 4, 5, 6. and 8, Article 75 paragraphs 1 and 5, Article 80, Article 81, Article 82, Article 83, paragraphs 1, 2, and 5 to 7, Article 84, paragraphs 4 to 6, Article 85, Article 86, paragraph 2, Article 87, Article 88, paragraph 1, Article 89, Article 90 t. 1 and 2, Article 91,. 1 and 5, Article 92, Section 97, Paragraph 2, Article 101, paragraph 7, Art. 117 and 125);
- 3) Present a medical device at a business fair, exhibition, presentation, etc. contrary to the provisions of Article 19, paragraph 2 of this Law;
- 4) Mark the medical device in contravention of this Law (Article 18, Article 19, paragraphs 3 and 4, Article 25, paragraph 4, Articles 35, 93, 94, 95, 114 and 125);
- 5) Conduct a clinical trial contrary to this Law (Article 29 paragraphs 1, 2 and 4, Article 30 paragraph 2, Article 31, Article 32, paragraphs 1, 3 and 4, Article 33, Article 37. paragraphs 4 and 5, Article 41, paragraphs 1, 2 and 7, Article 42, paragraph 2, Article 43, paragraph 1, Article 44, paragraphs 1 and 5, Article 47, paragraph 3, Article 48 and Article 49, paragraphs 1 and 3);

- 6) Do not carry out vigilance in accordance with Article 54, paragraph 6, Article 97, paragraph 2, Article 99, 2, 3 and 4 and Article 100, paragraph 5 of this Law;
- 7) Advertise a medical device contrary to the provisions of this Law (Article 104, paragraphs 5, 6 and 7, Article 108, paragraphs 2 and 3, Articles 109, 110, 111, 112, 113, 114, 115 paragraphs 2 to 8 and Article 116).

A fine of RSD 100,000 to 150,000 shall be imposed on a party responsible for the economic offense with the manufacturer of the manufacturer or an authorised representative of the manufacturer if they act contrary to the provisions of Article 51, paragraph 4, Article 53, paragraph 1, Article 54, paragraph 1 and Article 56 paragraph 3 of this law.

A fine of RSD 100,000 to 150,000 shall be imposed on a party responsible for the production and quality of the medical device with the entrepreneur if they act contrary to the provisions of Article 12, Article 17, paragraph 1, Article 19, paragraph 1, Article 22, 1 and 3, Article 25 paragraphs 1, 3 and 5, Article 34, paragraph 1, Article 36, paragraphs 1 and 2, Article 51, Article 57, Paragraph 1, Article 58, Article 60, Paragraph 6, Article 61, Paragraph 1 and 5, Article 65, paragraph 1, and Article 67 of this Law.

A fine of RSD 100,000 to 150,000 shall be imposed on a party responsible for the sale of medical devices with an entrepreneur if they act contrary to the provisions of Articles 52, 3 and 4, Article 69, paragraphs 3 and 4, Article 70, paragraphs 1 and 5, Article 71, paragraph 1, Articles 80, 81 and 82, Article 83, paragraphs 1, 2, 5, 6 and 7, Article 84, paragraphs 4 to 6, Article 85, Article 86, paragraph 2, Article 87, Article 88, paragraph 1, Article 89 and Article 92 of this Law.

A fine of RSD 100,000 to 150,000 shall be imposed on an offender responsible for vigilance with an entrepreneur of the manufacturer or an authorised representative of the manufacturer if they act contrary to the provisions of Article 54, paragraph 6, Article 97, paragraph 2, Article 99, 2 and 4 and Article 100, paragraph 5 of this Law.

A fine of RSD 100,000 to 150,000 shall be imposed for a misdemeanour referred to in paragraph 1 of this Article a natural person who performs an activity or performs the activity referred to in paragraph 1 of this Article as an unregistered entity.

Article 129

With the penalty referred to in Article 128 of this Law, the entrepreneur may also be imposed a protective measure of prohibition of performing a certain economic activity for a period of six months to three years.

In addition to the penalty referred to in Article 128 of this Law, an entrepreneur shall be obliged to impose a measure of confiscation of objects that were used or intended for the commission of a misdemeanour or which resulted from the commission of a misdemeanour.

Article 130

A fine of RSD 100,000 to 150,000 shall be imposed on a natural person for the misdemeanour, as follows:

- 1) A healthcare worker or coordinator for vigilance, if he/she does not inform the Agency and the manufacturer or authorised representative of the manufacturer about the incident of a medical device in accordance with Article 98, paragraph 2 and 99, paragraph 2 of this Law;
- 2) The lead researcher and member of the research team who undertakes any activity related to the clinical trial prior to the issuance of the approval for the conduct of a clinical trial by the Agency and the positive opinion of the Ethics Committee of Serbia (Article 32, paragraph 3);
- 3) A doctor who prescribes a medical device “off-label” in contravention of Article 96, paragraph 2 of this Law.

XIX TRANSITIONAL AND FINAL PROVISIONS

Article 131

Manufacturers based in the Republic of Serbia, authorised representatives of manufacturers, wholesalers, importers and specialised shops of medical devices are obliged to harmonise their operations with the provisions of this law and regulations adopted for its implementation no later than 12 months from the day of the beginning of application of this law.

Article 132

The licence for production, wholesale and retail trade of medical devices issued by the Ministry in accordance with the regulations that were in force until the date of application of this law is valid for a maximum of 24 months from the date of application of this Law.

Manufacturers, wholesalers and specialised shops of medical devices licenced to perform activities in accordance with the regulations in force until the date of application of this Law shall be obliged, within 24 months from the day of commencement of the application of this Law, to submit to the Ministry a request for issuing a license for performing activities of production, or trade in medical devices in accordance with this Law and regulations adopted for its implementation.

Article 133

The decision on entry in the Register of Medical Devices, i.e. the permission for placing on the market of a medical device, issued in accordance with the regulations that were valid until the date of the application of this Law, shall be valid until the expiration of the deadline specified in the decision on registration in the Register of Medical Devices issued by the Agency.

Manufacturers based in the Republic of Serbia and authorised representatives of a foreign manufacturer who do not meet the conditions for registration of a medical device in accordance with this Law shall, within 12 months from the day of commencement of the application of this Law, perform the assessment of the compliance of the medical device, or make the selection of the body for the conformity assessment that will be performed by the conformity assessment in accordance with this Law and the regulations adopted for its implementation, for placing on the market, or for use.

Based on the results of conformity assessment within the deadline referred to in paragraph 2 of this Article, the manufacturer, or an authorised representative of the manufacturer, is obliged to perform the registration of a medical device in the Republic of Serbia.

Notwithstanding paragraph 3 of this Article, if, within the deadline referred to in paragraph 2 of this Article, the appropriate body for assessment of conformity has not been appointed, the manufacturer with headquarters in the Republic of Serbia may renew the registration in the Register of Medical Devices or the Marketing Authorisation of medical devices in accordance with the regulations that were in force until the date of application of this Law, which ceases to be valid no later than 12 months after the beginning of the application of this Law.

Article 134

Manufacturers with headquarters in the Republic of Serbia, other than the manufacturers referred to in Article 59, paragraph 1 of this Law, shall, within 12 months from the day of commencement of the application of this Law, perform the assessment of the conformity of the production of the medical device, or make the selection of the conformity assessment body carry out a conformity assessment in accordance with this Law and the regulations adopted for its implementation.

Based on the results of conformity assessment referred to in paragraph 1 of this Article, the manufacturer or conformity assessment body issues an appropriate certificate of conformity submitted by the manufacturer with headquarters in the Republic of Serbia to the Ministry for the annulment of the production licence issued in accordance with the regulations that were in force until the implementation of this law.

A manufacturer based in the Republic of Serbia in the event of the cancellation of the production licence referred to in paragraph 2 of this Article, may at the same time submit a request to the Ministry for issuing a licence for the wholesale distribution of medicinal products it manufactures.

Article 135

The procedures initiated under the requests submitted to the Ministry or the Agency by the date of the application of this Law shall end according to the regulations that were valid at the time when the request was submitted.

Notwithstanding paragraph 1 of this Article, applications for entry in the Register of Medical Devices, or for issuing a licence for placing on the market of a medical device, submitted to the Agency by the date of the application of this Law shall be deemed to be requests submitted for the registration of medical devices if the applicant submits the necessary documentation in accordance with this Law and the regulations adopted for its implementation.

Article 136

The regulations for the implementation of this law shall be passed no later than 12 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 that were in force until the date of entry into force of this Law shall apply, and which are not contrary to the provisions of this Law.

Article 137

On the day this law enters into force, the Law on Medicinal Products and Medical Devices (“Official Gazette of the Republic of Serbia” No. 30/10 and 107/12) shall cease to apply in the part regulating medical devices for human use.

On the day this law enters into force, the provisions of the law governing health care regulating ethical committees in health institutions and the Ethics Committee of Serbia in the part relating to clinical trials of medical devices will cease to apply.

Article 138

This Law shall enter into force on the eighth day from the date of its publication in the “Official Gazette of the Republic of Serbia”, and shall apply 12 months after the date of entry into force, with the exception of Article 94, paragraph 5, which shall apply from the date of entry into force of this Law.

The provisions of Article 1, paragraph 9, Article 2, item 98), Article 15, paragraph 6, Article 50, paragraph 2, Article 69, paragraph 8, Article 80, paragraph 2, item 6) and Article 85, paragraph 2, item 8) will be applied as of the date of accession of the Republic of Serbia to the European Union.

On the date of accession of the Republic of Serbia to the European Union, the provisions of Article 82, paragraph 1, item 11 shall cease to apply.