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Based on Article 99 paragraph (7), Article 100 paragraph (4), Article 106 paragraph (5), Article 112 paragraph (3) and Article 113 paragraph (4) of the Medicinal Products and Medical Devices Act of Bosnia and Herzegovina ("Official Gazette of BiH", No. 58/08), the Minister of Civil Affairs of Bosnia and Herzegovina, at the proposal of the Expert Council of the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina, adopted

ORDINANCE
ON MEDICAL DEVICES

PART I - GENERAL PROVISIONS

Article 1

This Ordinance lays down the conditions and rules for the classification of medical devices, general and special conditions for placing a medical device on the market, depending on their purpose, the procedure for the conformity assessment of the medical device and procedure of, and the documentation required for, registration of a medical device in the register of the Agency for Medicines and Medical Devices of BiH (hereinafter: the Agency).

Article 2

(1) The terms used in this Ordinance, unless otherwise determined, have the following meaning:

a) invasive medical devices which penetrate the body through the skin, natural or artificial openings;

b) body orifice is every natural opening on the body, as well as the outer surface of the eyeball, or any permanent artificial opening (eg. stoma);

c) surgical invasive medical device is a medical device that goes inside the body through the body surface with the help of a surgical procedure;

d) implantable medical devices are products that surgically enter the body, or are partially implanted in the body to replace the surface of the epithelium or surface of the eye and remain in this place for at least 30 days after the procedure;

e) reusable surgical instruments are instruments used for cutting, drilling, sawing, scratching, turning, attaching or other similar procedures that are not related to any of the active medical devices that can be used after the completed surgical procedure;

f) active medical devices are those which effect depends on electricity or any other source of energy, gravity and which operate with the change of this energy, ie gravity;

g) active therapeutic medical devices are used separately or in combination with other medical devices;

h) inactive diagnostic medical devices are used separately or in combination with other medical devices and provide information for the detection of irregularities, diagnosis, monitoring or treatment of physical problems, diseases or congenital anomalies;

i) compliance statement of the medical devices is a statement by which the manufacturer confirms that the product, process or service corresponds to the prescribed requirements that are specified by standards or technical regulations;

j) clinical trial of the medical device is the determination or confirmation of the harmlessness of the medical device, its effectiveness and compliance with the general and specific requirements according to the purpose specified by the manufacturer.

(2) Other terms used in this Ordinance, other than those specified, and are defined by the Medicines and Medical Devices Act ("Official Gazette", No. 58/08 - hereinafter: the Act) and the Implementing regulations based on the abovementioned, accordingly apply to medical devices.

Article 3

(1) Medical devices, in terms of this Ordinance, are: instruments, devices, materials and other products that are applied on people and which principal intended action, determined by the manufacturer, is not achieved in or on the human body by pharmacological, immunological, or metabolic devices, but they are used alone or in combination, including software, for the purpose of:

a) Diagnosis, prevention, monitoring, treatment or alleviation of disease;

b) Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;

c) Investigation, replacement or modification of the anatomy or of a physiological process;

d) Control of conception.

(2) in vitro diagnostic medical devices include reagents, reagent kits, reagents products, materials for control and calibration, instruments and devices, equipment or systems, which are used alone or in combination with other medical device, and are intended for use in in vitro conditions, for examination of biological samples, including tissue samples obtained from the human body, in order to obtain the data:

a) on the physiological or pathological conditions;
b) on the the congenital anomalies;
c) on the safety and compatibility of potential transplant recipients;
d) on the information necessary to monitor the therapeutic effects.

(3) additional device that, by definition, is not a medical device, and indicates the product which in combination with the medical device allows the functioning of a medical device in accordance with its intended purpose.
(4) medical device manufactured by purchase orders for certain user is a medical device that has been developed in accordance with the instruction written by the relevant expert;
(5) medical devices intended for clinical investigation are products and devices used by health workers during the clinical trials.
(6) A medical device in or on the human body does not exhibit effectiveness based on its pharmacological, immunological or metabolic devices, but it may be assisted in its function by products that act in this way.

(7) The provisions of this Ordinance shall not apply to:
a) medical devices containing blood products;
b) transplants or tissues or cells of human or animal origin (except non-living animal tissue);
c) personal protective equipment in accordance with regulations.

PART II - CLASSIFICATION OF MEDICAL DEVICES

Article 4

(1) According to the level of risk they pose to the user, medical devices shall be divided into:
   a) Class I – medical devices posing a low level of risk to the user,
   b) Class IIa – medical devices posing a higher level of risk to the user,
   c) Class IIb – medical devices posing a high level of risk to the user,
   d) Class III – medical devices posing the highest level of risk to the user.

(2) Based on the nature of a medical device, its connection to an energy source and other characteristics, medical devices can be:
   a) non-invasive medical devices (which are not in contact with the user or are in contact only with intact skin);
   b) invasive medical devices (which penetrate the body through the skin, natural or artificial openings);
   c) active medical devices (which are used separately or in combination with other medical devices and provide data for the detection of irregularities, diagnosis, monitoring or treatment of physiological disorders, illnesses or congenital anomalies).

(3) Based on the duration of application in or on the human body, medical devices can be:
   a) Transient use (intended for continuous use no longer than 60 minutes);
   b) Short-term use (intended for continuous use for no more than 30 days);
   c) Long-term use (intended for continuous use for more than 30 days).

(4) „In vitro“- diagnostic medical devices are classified as follows:

a) "In vitro" - diagnostic medical devices which are used by qualified personnel and that are according to the type of assets divided into- List A and B;

b) "In vitro" - diagnostic medical devices for self-testing- List C;

c) other "in vitro" diagnostic medical devices- List D.

(5) According to the method and place of issuance, medical devices are classified into:
   a) medical devices which are issued on prescription / order only in pharmacies and specialized stores;
   b) medical devices which are issued without a prescription only in pharmacies and specialized stores;
   c) medical devices which are issued on prescription / order in hospital pharmacies;
   d) medical devices which are sold without a prescription in free sale;

(6) If the medical device is presented in combination with the medicinal product or in combination with the product from the free sale, the device is classified according to the primary purpose which is stated by the manufacturer.

Article 5

(1) Medical devices for in vitro diagnostics may be placed on the market only if they do not endanger the health and safety of patients, users and other people, and when properly manufactured, implanted, maintained and used in accordance with their intended purpose.

(2) Unless otherwise specifically prescribed, all the provisions of this Ordinance apply to the medicinal products for in vitro diagnostic use.

(3) In vitro medical devices, according to the purpose, place and manner of use, are classified into:

a) List A - diagnostic tools used only by qualified personnel:

1) Reagents and reagent products, including materials for control and calibration for determining blood groups (ABO system), rhesus factor, antibodies (C, c, D, E, e), Anticell etc.;

2) reagents and reagent products, including materials for control and calibration, detection, quantification and verification codes of HIV infections HIV-1 and 2, HTLV 1 and 2, hepatitis B, C and D in human material.

b) List B-diagnostic tools used only by qualified personnel:

1) reagents and reagent products, including materials for control and calibration for determining the following blood groups: the "anti-Duffu; and anti-Kidd ";

2) reagents and reagent products, as well as the materials for control and calibration for determining illicit erythrocyte antibodies;

3) reagents and reagent products, as well as the materials for control and calibration for determining and quantifying of similar infections: rubella, toxoplasmosis and others in human material;

4) reagents and reagent products, as well as materials for calibration and the control for diagnosing hereditary diseases (phenylketonuria);

5) reagents and reagent products, as well as the materials for control and calibration for the determination of human infections (cytomegalovirus, chlamydia);

6) reagents and reagent products, as well as the materials for control and calibration for determining "HLA"; - Tissue groups ("DR, A, B ');

7) reagents and reagent products, as well as the materials for control and calibration with control materials for determining tumor markers ("PSA");

8) reagents and reagent products, as well as the materials for control and calibration and software, for determining specificity of the hereditary risk of trisomy 21

c) List C-diagnostic tools for self-testing, the accessories for self-diagnosis, as well as materials for control and calibration (accessories for measuring sugar, etc.).

d) List of D-all other diagnostic tools.

Article 6

(1) The medical devices for special purposes are:

a) medical devices custom made for an individual user;
b) medical devices intended for clinical trials;
c) medical devices intended for scientific research and development.

(2) Documentation for medical devices for special purposes shall be submitted in the same manner as the documentation for all medical devices, provided that the declaration of a special purpose is added in accordance with the type of use.

PART III - RULES FOR CLASSIFICATION OF MEDICAL DEVICES

TITLE I - GENERAL RULES

Article 7

Rules for the classification of medical devices based on the conditions set out in Art. 2, 4, and 5 of this Ordinance, in accordance with which medical devices are classified in relation to:
a) the duration of the contact with the user;
b) the degree of risk in relation to the user;
c) the degree of invasiveness;
d) the purpose of the medical device;
e) the place of application;
f) the method of use of a medical device.

Article 8

(1) Application of the rules for the classification of medical devices is dependent on the use of of the medical device.

(2) In the case that a medical device is intended for use in combination with other medical device, the rules for classification apply to each product separately.

(3) The software that allows operation of a medical device or influences it automatically falls into the same class.

(4) In case that a medical device is not intended for use solely or principally on a particular part of the body, is classified in the indicated use with the highest risk, and the use with the application of the strictest rules of classification.

(5) In the event that for same medical devices applies more rules with regard to purpose and mode of action specified by the manufacturer, shall apply the strictest rules that result in classification in the higher class of medical devices.

TITLE II - CLASSIFICATION OF NON-INVASIVE MEDICAL DEVICES

Article 9

(Rule 1 - Medical devices that are not in contact with the user or are in contact only with intact skin)

Non-invasive medical devices, if fall under any of the following rules, shall be classified into:

Class I, such as:

1) medical devices for taking fluid from the body eg .: bottle or bag for urine collection, bag for "stoma", incontinence pads and the like;

2) medical devices which are used for the immobilization of body parts; eg .: plaster, splints, compression stockings and the like;

3) medical devices which are required for external assistance to patients; eg .: hospital bed, walking aids, wheelchairs, stretchers, dental chairs and the like;

4) corrective glasses, frames, prescription glasses, stethoscope, surgical covers, contact and conductive gels, non-invasive electrodes, computer equipment for image processing and the like.

Article 10

(Rule 2 - Medical devices for routing and perserving substances)

(1) Medical devices which are used for routing (transmitting) and preserving of substances, blood, organs, body parts, body fluids or tissues, liquids and gases for infusion, are classified into:

Class IIa, such as:
1) medical devices for routing (transmitting) of blood in transfusions;

2) medical devices for temporary preserving and transport of organs for transplantation or processing;

3) medical devices for long term storage of biological substances such as the cornea, sperm, tissue, and the like.

(2) If the medical devices can be connected to an active medical device from the class IIa, or higher class, may be indirectly invasive, and according to the degree of risk for users belong to the upper class, such as:

a) Medical devices which are used as a router in an active drug delivery system (systems which are used with infusion pump);

b) Medical devices which are used for routing in respiratory system for anesthesia, pressure indicators, devices for limiting the pressure;

c) A syringe (nozzle), infusion pumps.

(3) In all other cases, medical devices mentioned in the previous paragraph shall be classified as Class I, such as:

a) devices for routing when the force for the transfer of liquids originates from gravity (delivery systems for infusion or medicines, etc.);

b) devices for temporarily weighing and storage (bowls and spoons made specifically for

administration of medicial products, etc.);

c) syringes without needles.

Article 11

(Rule 3 - non-invasive medical devices which alter the biological or chemical composition of blood, body fluids or other fluids)

(1) All non-invasive medical devices designed to change the biological or chemical composition of blood, other body fluids, which are intended for parenteral use and may be indirectly invasive, are classified as:

Class IIb, such as:

1) The products intended for the removal of undesirable substances from the blood (devices for hemodialysis, dialysis systems, autotransfusion, etc.);

2) The products intended for the separation of cells.

(3) Medical devices used for filtration, centrifugation or exchange of gas and heat, are classified as:

Class IIa, such as:

1) devices for filtration of blood components;
2) devices for centrifugation of blood as a preparation of blood for transfusion or autotransfusion;

3) devices for heating and cooling the blood in extracorporeal circulation.

Article 12

(Rule 4 - Medical devices which are in contact with damaged skin)

All non-invasive medical devices that come into contact with damaged skin are classified into:

a) Class I;

If used as a mechanical barrier for compression or for absorption of fluid from wounds, such as wound bandages, wound dressings and the like.

b) Class IIa;

In all other cases, including medical devices, together with the physical devices designed for wound healing, and which have special properties due to the regulation of humidity and temperature, such as glue for local use, bandages with polymer coating, hydrogel bandages and soaked gauze bandages that do not include medicines and the like;

c) Class IIb,

If used for wounds with damaged skin layer where only secondary wound healing is possible, such as binders for ulcerated chronic wounds, for severe burns that affect a large area of skin, bandages for wounds that contain devices for regeneration of tissue, and provide a substitute for the skin and the like;

d) Class III,

All non-invasive medical devices that contain medicinal products or inanimate animal tissue.

TITLE III-CLASSIFICATION OF INVASIVE MEDICAL DEVICES

Article 13

(Rule 5 - invasive medical devices which are used in the orifices)

All invasive medical devices which are used in natural orifices and the openings occurred as a result of surgical intervention on body surface area, in addition to surgical invasive medical devices that are not designed for connection to an active medical device, are classified into:

a) Class I:

1) if they are designed for transient use, such as dental mirrors, materials for making prints in the dentistry, gloves for the examination of the patient and the like;

2) if they are used in the oral cavity to the throat, in the ear canal to the eardrum, or in the nasal openings.

b) Class IIa:

1) if they are intended for short term use, such as contact lenses, urinary catheter, tracheal tube, a stent and the like.

2) if are used in the oral cavity to the throat, in the ear to the eardrum or in the nasal cavity, such as orthodontic wire, fixed prosthetic dental prostheses and restorations, devices for fillings;

3) invasive medical devices which are used in body orifices, other than surgically invasive medical devices designed for connection to an active medical device from the class IIa or a higher class, such as tracheal tube, cannula for tracheotomy, mechanical flush on the nose, naso-pharynx tube, nasogastric tube, aspiration catheters and the like.

c) Class IIb:

If they are intended for long-term use, such as: "supports", the stent for the urethra, and the like.

Article 14

(Rule 6 - Surgical invasive devices for short-term use)

(1) The surgical invasive devices include three main groups of medical devices:
a) medical devices for the preparation of passage through the skin;
b) surgical instruments;
c) the various types of catheters.

(2) All surgical instruments are classified into:

a) Class I:

Surgical instruments for multiple or repeated use, such as scalpels, saws, pliers for refraction and the like;

b) Class IIa:

Surgical instruments designed for single use, such as needle suture, injection needle, lancets, disposable scalpels, surgical swabs, drill tip if they are connected to an active medical device, surgical gloves and the like.

c) Class IIB:

1) medical devices designed for bringing energy in the form of ionizing radiation;

2) bioactive medical devices which by biological influence actively cause tissue response to the level of molecule;

3) medical devices which are intended for the administration of medicinal products by with the help of devices for the application, the use of which could be dangerous for the patient, as well as the medical devices for the self-dosing which contains medicinal products, such as insulin pens - injectors and the like.

d) Class III,

If the medical devices are designed for diagnosis, monitoring of cardiac damage or systemic circulation of the central blood system, such as cardiovascular catheters and associated guidewires, vascular surgical instruments made for single use and the like.

Article 15

(Rule 7 - Surgical invasive devices which are intended for short-term use)

Surgical invasive devices which are intended for short-term use in surgery or as part of post-operative care are classified into:

a) Class IIa,

All invasive surgical products which are suitable for short-term use-couplers, infusion cannula, suture products, except further mentioned exceptions.

b) Class IIb,

1) medical devices that provide energy in the form of ionizing radiation, such as accessory for brachytherapy;

2) medical devices which undergo chemical changes in the body, except those that are implanted in your teeth or are used for administration of medicinal products, such as adhesives and the like.

c) Class III,

1) clamps, infusion cannula, auxiliary suture and the like;

2) medical devices for determination of diagnosis, for the control of damage to the heart or circulatory system and which are in direct contact with these parts of the body, such as vascular catheter probes for determining cardiac output, electrodes for temporary excitation of the heart;

3) medical devices which are in direct contact with the central nervous system, such as neurological catheter, cortical electrodes; medical devices which are completely or mostly absorbed in the body, such as the resorption thread and biological adhesives, and the like.

Article 16

(Rule 8 - Surgical invasive devices for long-term use and implantable medical devices)

(1) These are generally implantable medical devices, which are used long term (implants in orthopedics, dentistry, ophthalmology and cardiovascular medicine, and the implants for incorporation of soft tissue used in plastic surgery).

(2) All surgical invasive implantable medical devices used long term are classified into:

a) Class IIa,

If they are intended for use in the mouth, such as dental veneers, dental materials, pins, stopper, dental alloys, dental porcelain and polymers, fixed prosthetic denture and the like.

b) Class IIb,

Surgical invasive medical devices for implantation and invasive surgical products used long term, eg implants for joints, bindings, Santo, stents, screws, plates, intraocular lenses, extensions for infusion, transplants of peripheral blood vessels, bone cement, Maxillofacial transplants and the like.

c) Class III,

1) medical devices in direct contact with the heart, the main bloodstream and central nervous system; artificial heart valves, clamps for aneurysm, prostheses for blood vessels, supports of the spine, support for blood vessels, stents, electrodes for the central nervous system, cardiovascular stents and the like;

2) medical devices intended for the production of biological material for the complete or incomplete absorption, such as the resorption threads, adhesives, and implantable auxiliary devices which are said to have the additional bioactive coatings, phosphorylcholine and the like;

3) medical devices which can experience chemical changes in the body, such as inactive systems for administration of medicinal products that may be recharged.

TITLE IV-CLASSIFICATION OF ACTIVE MEDICAL DEVICES

Article 17

(Rule 9 - Active medical devices which are intended for the supply or exchange of energy)

(1) Active medical devices which are classified by this rule are:

a) Electrical equipment used in surgery;
b) Lasers and generators;

c) Accessories for specialized treatment, for example for radiation;
d) Stimulating accessories;

e) Other similar medical devices intended for the supply or exchange of energy.

(2) All active medical devices intended for supply or exchange of energy are classified into:

a) Class IIa,

1) muscle stimulators, external stimulators of bone growth, stimulators for pain, magnets for removing foreign particles from the eye which operate on the basis of electrical, magnetic, electromagnetic energy;

2) medical devices for performing phototherapy for the treatment of skin diseases and post-natal care of the newborn, which operate on the basis of the light energy;
3) heating pads, equipment for cryo-surgery, operating on the basis of thermal energy;
4) motor dermatomes, drills for dentists who operate on the basis of mechanical energy;
5) hearing aid products which operate on the basis of sound.

b) Class IIb,

Medical devices which uses are risky for the patients, and operate on the basis of:
- Kinetic energy (lung ventilators);

- Thermal energy (heating of blood, incubators, heating pad for patients who are unconscious);

- As well as bandages, bandage for bleeding, bleeding from the nose or from the dental Protolytic prosthesis;

- Electric power (high-frequency electrical generators in surgery, equipment for electrocautery, external actuactor of the heart, external defibrillators, equipment for electro-treatment - electroconvulsive treatment);
- Coherent light (lasers in surgery);

- Ultrasound (lithotripters);

- Ionizing radiation (radioactive sources for the treatment by the load of the body, therapeutic cyclotron, linear accelerators, sources of X-rays);

- Active medical devices intended for the control and monitoring of action of active medical devices (external feedback systems for active medical devices, or devices to control the load of the body).
Article 18

(Rule 10 - Active diagnostic medical devices)

(1) Active medical devices, which fall within the scope of ultrasound diagnosis, monitoring of physiological signals, in the field of therapeutic and diagnostic radiology, are classified into:

a) Class IIa:

1) if they are intended for bringing the energy that should be absorbed by the human body, such as testing equipment with a magnetic resonance imaging, the auxiliaries for the pulp, diagnostic ultrasound and the like;

2) if they are intended for in vivo imaging of radiopharmaceutical layout, such as gamma - cameras, positron emission computed tomography, and the like;

3) if they allow the simultaneous diagnosis, such as electrocardiographs, electroencephalography, cardioscope with the cursor beats.

b) Class IIB:

1) if they are intended for ionizing radiation for diagnostic and therapeutic radiology intervention, such as sources of X-rays for diagnosis;

2) if they are intended to control the important life functions, in which the nature of such changed that could endanger patients, such as: changes in the functioning of the heart, respiration, activity of the central nervous system (systems for the control of patients in intensive care, gas analyzers in the blood and the like).

Article 19

(Rule 11 - Active medical devices for administering medicinal products and other substances in the body or for their removal from the body)

Active medical devices for administering medicinal products and other substances in the body or for their removal from the body are classified into:

a) Class IIa:
Drain and supply pumps,

b) Class IIb

Medical devices for administering medicinal products and other substances in the body or for their removal from the body, which are applied in ways that could be dangerous for patients, such as infusion pumps, equipment for anesthesia, dialysis equipment, blood pumps in artificial heart , hyperbolic chambers, devices for regulating pressure in medical gases and the like.

Article 20

(Rule 12 - Other active medical devices)

Additional rule 12 includes all active medical devices that are not covered by the previous rules, and they are classified into:

Class I:

1) active medical devices intended to illuminate the patient's body in the visible light spectrum, such as: lamps for the examination of the patient, or for optical examination of the body, such as surgical microscopes and the like;

2) medical devices intended for external help to patients, such as elevators for patients, wheelchairs and the like;

3) active diagnostic products for thermography;
4) active products for the recording, processing or examination of diagnostic images;
5) polymerization lights in dentistry.

TITLE V - SPECIAL RULES FOR CLASSIFICATION

Article 21

(Rule 13 - Medical devices which contain medicinal products - active substances)

This rule includes the combined medical devices which contain as an integral part medicinal product for an additional effect on the body alongside with the actions of the medical devices themselves. Medical devices which contain medicinal products or medicinal substances are classified as:

a) Class III:

Bone cement containing antibiotics, bandages containing medicine, condoms with spermicide, heparin catheter, endodontic materials containing antibiotics and the like.

Article 22

(Rule 14 - Medical devices used for contraception or prevention of the spread of sexually transmitted diseases)

Shall be classified into:

a) Class IIB:

Medical devices for the prevention of pregnancy (contraception) or prevention of the spread of contagious sexual diseases, such as condoms, vaginal diaphragms, and the like.

b) Class III:

Implantable medical devices or invasive medical devices for long-term use, such as intrauterine devices and the like.

Article 23

(Rule 15 - Special medical devices for disinfecting, cleaning and rinsing)

(1) All medical devices which are used for disinfecting, cleaning and rinsing, and moisturizing contact lenses are classified into:

a) Class IIa:

Medical devices intended for disinfecting medical devices, medical equipment, work surfaces in health care facilities or for disinfection of living tissue (antiseptics). Eg. disinfectants for endoscopy, the apparatus for sterilization

b) Class IIB:

Medical devices intended for disinfecting, cleaning and rinsing, and moisturizing contact lenses.

(2) This rule does not apply to products intended for mechanical cleaning of medical devices.

Article 24

(Rule 16 - Inactive medical devices which are used for the registration of X-ray images)

Inactive medical devices which are used for the registration of X-ray images.

Class IIa:

Labeling of the X-ray images, such as X-ray film, photo-stimulating phosphor plates and the

like;

(3) This does not include devices used for reproducing the X-ray image.

Article 25

(Rule 17 - Medical devices containing inanimate animal tissues)

All medical devices, which contain inanimate animal tissues or are created out of it or contain derivatives of such tissues, are classified into:

a) Class I:

Medical devices created from inanimate animal tissue, which are only in contact with intact skin, such as leather parts of orthopedic devices, derivatives of inanimate animal tissue, which does not contain active substances (milk, silk, beeswax, hair, lanolin and the like).

b) Class III:

The biological heart valves, bandages with porcine heterotransplant, catgut sutures, implants and binders from collagen fibers and the like.

Article 26
(Rule 18 - Blood bags)

(1) Notwithstanding the provisions of the earlier classification rules, this rule covers only blood bags, including bags containing a solution for preserving the blood, and are categorized as Class II b.

(2) In the case that blood bags have a role that includes not only blood storage by the solution for storing, other rules may be used, for example, Rule 13, which applies to medical devices that contain medicinal active ingredient and are classified in Class III.

PART FOUR - Register of Medical Devices

Article 27

The Agency shall issue a certificate and keep a register of medical devices, which comprises:
a) Register of medical devices of Class I;

b) Register of medical devices of Class IIa, IIb, and III;
c) Register of in vitro - diagnostic medical devices;
d) Register of the manufacturers of medical devices;
e) Register of Legal Persons-distributors of medical devices in BiH

Article 28

(1) The requirements for registration "referred to in paragraph (1) items a), b) and c) of the previous Article," is considered by the Committee for medical devices, which among prominent medical and other experts, are appointed by the Director of the Agency, with the prior approval of the Expert Council .

(2) The Committee for medical devices is autonomous and independent in its work, and performs tasks on the basis of the Rules of Procedure, and is entitled to fees for its work, the amount which is determined by the Director of the Agency, in accordance with regulations that regulate this issue.

(3) The Committee for medical devices evaluates the documentation provided in the process of registration in the register of medical devices.

(4) The Committee for Medical Devices has nine members. Entity ministries propose by four members and the Department of Health of Brcko District one member.

PART FIVE - PRODUCTION OF MEDICAL DEVICES

Article 29

The manufacturer of a medical device is required in the production process, to ensure the application of technical regulations on the safety of products on the market, the application of the code of Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP) and good storage and transportation practices in order to protect the safety and health of the consumers.

Article 30

(1) The manufacturer of medical devices should, in addition to general legal requirements, comply with the special requirements determined by the Act, as follows:

a) report its activities to the Agency before the commencement of production of the medical devices;

b) carry out the activities while ensuring quality system and all good practices, in order to fully protect the health of the population, as determined by the "GMP" inspector of the Agency

c) meet the prescribed conditions in regarding the staff, premises and equipment, in the proceedings with the competent entity`s Ministries of Health, and the Department of Brcko District, on the basis of which, after the completion of the process, it obtains a certificate of registration in the register of manufacturers of the medical devices issued by the Agency, without which cannot begin the activity of production of medical devices;

d) obtain an insurance for any damage caused to the user or third party.

(2) Pursuant to the Act, the entities and the District of Brcko shall prescribe specific conditions relating to premises, equipment and staff of the manufacturer, on the basis of which they shall adopt a decision on the compliance with the same, as a prerequisite for the issuance of the certificate of registration in the register of manufacturers of medical devices by the Agency.

(3) The manufacturer of the medical devices during the process of the development of medical devices should use technical regulations that ensure compliance of medical devices with the general and specific requirements.

(4) The manufacturer of a medical device should ensure the conditions for testing and quality control of each batch of products in their own or another authorized laboratory that meet the requirements relating to good laboratory practice.

Article 31

(Report of production activities of a medical device)

(1) The manufacturer of a medical device shall submit to the Agency a completed application form (applications) of production activities, with taxatively listed documentation, and from which, after the control of the competent inspector of the Agency may conclude that the medical device is produced while ensuring quality system and health protection of the population, and that the medical devices are produced by general and specific requirements.

(2) Implemented quality assurance system in the production facility of the medical device shall be demonstrated by the corresponding "ISO" certificate of quality system issued by the competent certifying house in BiH.

(3) The manufacturer of the medical device shall submit to the Agency the description of the manufacturing process, proof that it is the legal person and the list of individual medical devices for which it is applying for a license for production, evidence of quality control and maintenance methods of production space and equipment.

(4) The manufacturer a medical device shall submit to the Agency documentation of any changes of production processes and specifications of a medical device, and other data relating to public health.

Article 32
(The procedure for registration of manufacturers of medical devices in the Register)

(1) An application for registration of the manufacturer of medical devices in the Register begins by completing the form of the Agency-Annex 4 of the Ordinance which contains taxatively enumerated necessary documentation.

(2) The application should contain the subject of the application, date, and name of the applicant and the place of production, the name and signature of the responsible person.

(3) The Agency shall consider only complete applications in accordance with the provisions of this Ordinance. If the application is not complete, the Agency shall notify the applicant in writing to complete it within a period not exceeding 15 days from the date of receipt of the notification. In the event that the applicant does not complete the application within the specified time limit, the Agency shall refuse the request.

(4) After a complete formal request, "GMP" inspector of the Agency shall further control the quality system and the requirements of good manufacturing practice in the production facility, after which he/she encloses the record of determined conditions, on the basis of which the certificate of registration in the Register of the manufacturers of medical devices is issued or the request is rejected.

(5) The certificate on registration in the Register of the manufacturers of medical devices, the Agency shall issue within 30 days of receipt of a complete application.

(6) The certificate of registration in the Register of the manufacturers of medical devices shall be issued for a period of 5 years and it is issued only for manufacturers based (place of production) on the territory of BiH.

(7) The certificate 'referred to in paragraph (5) of this Article "is final and against the same cannot be appealed, but an administrative dispute before the competent court within 60 days of receipt.

(8) The manufacturer by the registration in the Register the manufacturers in BiH acquires the right to manufacture medical devices in Bosnia and Herzegovina.

(9) The costs of issuing the certificate on registration, changes and deletion from the Register of manufacturers of medical devices shall be borne by the applicant.

Article 33

(1) The production of medical devices should not be carried out until the registration in the Register of manufacturers of medical devices is approved.

(2) The manufacturer is responsible for the manufacture, placing on the market and for any consequences in the application of medical devices.

(3) The manufacturer shall, without delay, inform the Agency of any changes or errors in the

production process, quality control, as well as other situations that might question the quality, safety and effectiveness of the medical devices.

(4) In the cases "referred to in paragraph (3) of this article," the Agency may prohibit the production and marketing of the medical devices, or order the withdrawal of the medical device from the market.

(5) Legal persons shall be deleted by the Agency from the Register of manufacturers in cases of:

a) the decision of the competent authority that the legal person does not meet the requirements for this activity in accordance with the regulations;
b) a written request of the applicant;
c) termination of the legal person in the cases stipulated by a special law.

PART SIX - TESTING OF MEDICAL DEVICES

Article 34

Testing of medical devices is conducted due to determining or confirming the effectiveness, safety and quality, in accordance with the declared application specified by the manufacturer.

Article 35

(1) Clinical trials of medical devices is determining or confirming the harmlessness of the medical device, its efficiency and compliance with the general and specific requirements according to the purpose specified by the manufacturer.

(2) Side effects and clinical trials of the medical devices are regulated by the Ordinance on side effects and the Ordinance on clinical trials.

Article 36

(1) Quality control of medical devices involves determining the prescribed quality of these devices in accordance with this Ordinance and the Act.

(2) The quality of the medical device shall be determined by regular, specific, systematic and extraordinary control in accordance with the provisions of this Ordinance and the Act.

(3) Control "referred to in paragraph (2) of this Article," may be ordered by a person authorized in accordance with the Act.

PART SEVEN - ESTABLISHMENT OF CONFORMITY AND LABELLING OF MEDICAL DEVICES

TITLE I - GENERAL ON ESTABLISHING THE CONFORMITY

Article 37

(1) The process of establishing the conformity of the medical device with the general and specific requirements of the Act is a procedure that directly or indirectly determines whether a medical device meets the requirements prescribed by the General Product Safety Directive, Law on Technical Requirements for Products and Conformity Assessment with the Act and regulations adopted pursuant to these laws.

(2) The process of establishing the conformity of the medical device with general and special requirements depends on the classification of the medical device according to the degree of risk, namely:

a) for Class I medical devices - manufacturer itself assesses the compliance of the product

with the general and specific requirements and, on their own responsibility, makes a statement or certificate based on that. Exceptions are class I medical devices that are used to measure and sterile products that are adjusted, which are treated as medical devices from class IIa, IIb and III for determining their ability to measure or sterility;

b) for medical devices from class IIa, IIb and III - the competent institution determines the compliance of medical devices with the prescribed general and special requirements, as well as the supervision of the quality assurance system.

(3) In cases where conformity assessment of particular types of medical devices is not performed by authorized institutions under the Law on Technical Requirements for Products and Conformity Assessment, assessment of their compliance will be assumed by the Committee for medical devices based on approval of the Expert Council, on a proposal of the Director of the Agency.

(4) In accordance with the existing regulations, the Minister of Civil Affairs of BiH on the proposal of the Expert Council shall determine the requirements regarding conformity assessment of a particular types of medical devices with the general and specific requirements under the Law and regulations "referred to in paragraph (1) of this Article" the procedure of labeling the medical devices, as well as the content of the certificate of compliance of the medical device.

Article 38
(Labeling of the medical device)

(1) Based on the compliance certificate, the manufacturer of the medical device is required to label the product by the prescribed designation of compliance.

(2) The Ministry of Foreign Trade and Economic Relations BiH on the proposal of the Agency prescribed the appearance of the designation of compliance which is used in BiH and the content of the certificate of compliance issued in BiH, unless otherwise prescribed by special law.

(3) An exception to the provision of "paragraph (2) of this Article," is the manufacturer of the medical device, whose conformity with the general and special requirements is determined by the authority for determining compliance which is recognized in the EU and such a medical device should be labeled with the CE mark.

(4) CE mark or certificate of compliance implies compliance with the requirements and directives of the European Union, as well as the application of good practices in the production, quality assurance, packaging, labeling and storage. (Good Manufacturing Practice and Good Laboratory Practice).

(5) The New Approach directives that require the CE mark set on products, in order to prove that the product is safe for use by humans, animals and the environment, which are proposed for adoption by the Ministry of Civil Affairs of Bosnia and Herzegovina.

(6) It is prohibited to label a medical device by designations foreseen in this Article, if it is not in accordance with regulations under Article 101 of the Medicinal Products and Medical Devices Act and regulations adopted thereunder.

Article 39

It is unnecessary to label medical devices:
a) intended for the clinical trial;
b) custom made for the individual patient or user.

TITLE II - BASIC REQUIREMENTS FOR MEDICAL DEVICES-GENERAL AND SPECIAL REQUIREMENTS FOR MEDICAL DEVICES

Article 40

(1) Medical devices shall meet the general regulations and technical requirements for products and conformity assessment regulations on general product safety, as well as the general and specific requirements determined by this Ordinance:

(2) General requirements: medical devices shall meet the general requirements as follows:

a) That the medical devices are designed, manufactured, implanted and maintained so when used according to the instructions, they ensure the quality, efficiency and safety for the user;

b) That in the production or part of the production at all stages when developing a secured system of quality in terms of design and production of the medical device.

(3) Special requirements: the requirements to be met by medical devices in order to enable their actions in relation to the purpose for which they were manufactured.

(4) The documentation for the pharmaceutical, clinical and other types of tests for medical devices that do not have a certificate of compliance with the directives of the European Union (CE), are prepared by the manufacturers.

Article 41

(1) Statement of Compliance is a statement by which the manufacturer confirms the application of the quality assurance system in the process of designing, manufacturing or part of the production, manufacturing, packaging, labeling, purpose or use, or a statement that the medical device corresponds to the prescribed requirements of this Ordinance.

(2) Elements of quality should be confirmed and documented, for each stage of production and trade, and for the sterile products for the sterilization phase also.

Section A - General requirements

Article 42

Medical devices should be:

a) designed and created so that, when used under the conditions that are stated by the manufacturer, do not compromise the clinical condition and safety of users and other persons;

b) an acceptable relationship between the benefits and risks;
c) effective, efficient and safe for the user according to the manufacturer;

d) designed and packaged so that, according to the purpose, are suitable for use by eliminating the risk or its reduction to a minimum;

e) created with an acceptable safety measures, including the introduction of an alarm in connection with the risk that may not be eliminated.

Article 43

(1) In the production process manufacturers need to take into account scientific and technical achievements in the field of medical devices, in compliance with the following principles:

a) the effectiveness of medical devices shall not be affected by other factors that may jeopardize the clinical condition and safety of users or other persons within the durability under the prescribed storage conditions, transport and use;

b) the acceptable safety measures, including the introduction of an alarm in connection with the risk that may not be eliminated;

c) informing users and other persons about the possible risk that cannot be eliminated by protective measures.

(2) Medical devices should be formulated, designed, made and packaged in accordance with the provisions "of paragraph 1 of this Article," so that their properties and effectiveness are completely preserved until the identified expiry date and that they are not affected negatively by other means which come into contact in the process of transportation, storage, traffic or use.

(3) The degree of risk of all unwanted and adverse effects of medical devices should be acceptable in relation to the desired object and purpose of use indicated by the manufacturer.

(4) The manufacturer or distributor is obliged to report to the Agency any observed undesirable and harmful effects of medical devices.

(5) The obligation of manufacturers, distributors and medical institutions is to monitor undesirable and harmful effects of medical devices and to report them to the Agency.

Section B - Specific requirements

Article 44

Medical devices shall meet the specific requirements:

a) in relation to the chemical, physical and biological properties of the medical devices;

b) in relation to microbiological quality of the medical devices;
c) in relation to the environment;
d) medical devices with a measuring function;
e) in relation to the radiation protection;

f) medical devices which are connected to a power source;
g) active medical devices which are implanted in the body;
h) in relation to the labeling of medical resources and instructions for use.

Article 45
(Chemical, physical and biological properties of medical devices)

Medical devices with respect to chemical, physical and biological properties should be:
a) effective and safe for the user and the therapist;

b) compatible with biological tissues, cells and body fluids with which they come into contact;

c) non-toxic, or acceptably toxic in relation to the object and purpose of use;
d) non-flammable, and applicable according to the intended use;

e) formulated, manufactured and packaged in such a way that they may be safely used in relation to materials and gases with which they come into contact during use;

f) compliant with the regulations on medicinal products, if they contain a medicine in its composition;

g) formulated, manufactured and packaged in such a way that the risk is reduced to a minimum, if the medicine would evaporate (leak) from the medical device;

h) formulated and manufactured in such a way that the risk to users and the environment, which could occur during entering of the unintended substances into the medical device, does not exist or is reduced to a minimum.

Article 46

(Requirements in relation to the microbiological quality of medical devices)

(1) Medical devices in relation to the the microbiological quality should be:

a) designed and manufactured so that the risk of infection to the user and others does not exist or is reduced to a minimum;

b) designed from the healthy tissue of animals that have been subjected to the appropriate veterinary examination and supervision, which is documented by the certificate;

c) sterile, formulated, created and packaged in disposable packaging, which provides that, under the prescribed conditions of storage and transport, they remain sterile until the expiration of the period of use;

d) designed a sterilized by an appropriate validated method for sterile conditions;

e) packaged in a container of appropriate quality, to ensure protection against microbial contamination at all stages, from production to the use;

f) labeled on the packaging or label so that it allows distinguishing between sterile and non-sterile products.

(2) The Agency shall keep records of the origin of animals and certificates about the quality of the tissue that is part of a medical device, or makes its principal part.

(3) The procedures of processing, preservation, testing and handling of tissues, cells and substances of animal origin shall be carried out so as to ensure optimal security, particularly with regard to transmission of infection by viruses and other pathogens.

(4) Production processes shall include methods of viral inactivation and other necessary methods.

Article 47

(Requirements for the medical devices in relation to the environment)

(1) If the medical device is intended for use in combination with other device or equipment, the quality system should ensure overall efficiency and safety.

(2) Any restrictions on of usage shall be indicated on the packaging or in the instructions for use.

(3) Medical devices should be designed so as to eliminate or at a minimum reduce:
a) the risk of injury in connection with their physical properties;

b) the risk associated with predictable environmental conditions such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure or acceleration;

c) the risk of cross-reactivity with other medical devices which are commonly used for

testing or performing the treatment;

d) the risk arising from the inability of maintenance or calibration of the medical devices.

(4) Medical devices should be designed so that the risk of fire or explosion, in terms of their application agrees with the declared use by the manufacturer, as well as in terms of mistakes made during use, reduced to a minimum.

(5) Special attention should be paid to medical devices that are during use exposed to flammable substances or materials which may cause burns.

Article 48

(Medical devices with a measuring function)

(1) Medical devices with a measuring function should be designed so as to provide sufficient accuracy and stability within the limits specified by the manufacturer.

(2) The manufacturer shall indicate the limits of accuracy of the measurement functions.

(3) Measuring, monitoring on the monitor and scale on the screen shall be designed in accordance with the activity, purpose and use of the medical device.

(4) Measurement which is performed by using the medical device with a measuring function should be expressed in units of measurement which have been adopted in Bosnia and Herzegovina.

Article 49
(Protection against radiation)

(1) Medical devices should be created so that the exposure of users and other persons to radiation is reduced to a minimum, but not limited to therapeutic and diagnostic purposes.

(2) From the point of application of the medical device, radiation exposure may be intentional or unintentional.

(3) Protection against intentional exposure to radiation:

a) in the case when medical devices are formulated to emit dangerous amounts of radiation that is needed for the treatment or diagnosis (in which the benefits outhweight the risks) the user should be able to control the amount of radiation;

b) the design and manufacture of such medical devices shall ensure reproducibility and tolerance of relevant variable constants;

c) in the case when the medical devices intended for radiation of potentially hazardous visible or invisible radiation, they shall be equipped with protecting shelter or warning systems for the radiation, if possible.

(4) Protection against unintentional radiation:

a) Medical devices shall be formulated and designed so that the exposure of users and other people to unintentional or dispersible radiation is reduced to a minimum;

b) the instructions for use of the medical device that radiates (ionizing rays) shall have accurate and verified information on:
1) the nature of radiation;
2) the means to protect users and others;
3) how to prevent incorrect use of the product due to radiation;
4) methods for the elimination of the risk when using the product.

(5) In addition to the requirements referred to in "paragraph (2) and (3) of this Article," medical devices which emit ionizing rays, according to the purpose should be:
a) formulated and created to provide control of the quantity, direction and quality of radiation;

b) intended for diagnostic radiology, formulated and designed so as to achieve adequate image quality or text, and to reduce the irradiation of users and other persons to a minimum;

c) intended for therapeutic radiology, formulated and designed to allow secure monitoring and control of the received doses of radiation, a type of air and energy, and in certain cases the quality of radiation.

Article 50

(Requirements for medical devices that are connected to a power source)

(1) Medical devices that are connected to a power source should meet specific requirements with respect to their application, namely:

a) medical devices containing electronic systems that can be programmed, should be designed to ensure the repeatability, safety and effectiveness of these systems during the application;

b) in the case of a fault in the system, there should be the means to eliminate or reduce the risk to a minimum;

c) medical devices in which the user's safety depends on an internal power supply shall be equipped with means for determining the status of the power supply;
d) medical devices in which the safety of users depends on the external power supply shall have alarm systems that inform about the power failure;

e) medical devices intended for monitoring of one or more clinical parameters in patients, should be equipped with appropriate alarm systems to alert the user in case of the events that could cause a deterioration of the health condition of patients or death;

f) medical devices should be formulated and designed so that the possibility of the electromagnetic field is reduced to a minimum, in order to avoid interference with activities of other medical devices or equipment around;

g) medical devices should be formulated and designed so that, in terms of the declared use of the manufacturer, as well as in terms of errors during the application, the risk of electric shock is avoided to the greatest extent possible.

(2) Protection against mechanical and thermal risks:

a) medical devices shall be designed and formulated so as to protect the patient and users from mechanical risks, for example, connected with the substrate (base), stability and moving parts;

b) medical devices should be formulated and designed so that the risk resulting from vibrations caused by these products, unless vibrations are part of a special activity of the product, is reduced to a minimum;

c) terminals and connectors for power supply, gas, hydraulic or pneumatic devices that are handled by the user, shall be designed and built so as to eliminate all possible risks;

d) the accessible parts of medical devices, with the exception of parts which are intended for bringing the heat or achieving the given temperature, as well as their environment, should not be heated during their normal application to potentially dangerous temperatures.

(3) Protection against risk in the supply of power or materials to the user:

a) medical devices that bring energy or material should be formulated and designed so that the energy flow may be set and maintained accurately enough to guarantee safety of the users;

b) medical devices shall be equipped with the means for preventing errors and / or warning in case of errors in the flow of energy that could pose a threat;

c) medical devices should be customized so that the greatest extent possible prevent unfavorable release of dangerous levels of energy from an energy source or sources of the materials.

(4) The functions of switches and indicators on medical devices should be clearly stated, in writing or in the form of images, so that they are understandable to people who apply medical devices, as well as for the users.

Article 51

(Special requirements for the active medical devices for implantation into the organism-body)

(1) Active medical devices for implantation into the organism (body) should be formulated, produced, created and packaged according to the generally recognized scientific and technical development in order to provide efficiency and safety for the user and other persons.

(2) Medical devices "referred to in paragraph (1) of this Article" should be created and packaged under special conditions in disposable packaging, which ensures the sterility of the medical device until the expiry date, opening or damage to the protective packaging and transport, according to the prescribed conditions, so that they eliminate or reduce to the greatest extent possible:

a) the danger during implantation in the body in relation to the physical properties of active medical devices;

b) the risk related to the energy source, especially for the active medical devices that are implanted by using electricity;

c) risks associated with the use of energy sources such as magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure and acceleration;

d) risks associated with treatment, especially when using defibrillators or high-frequency surgical equipment;

e) risks associated with the radiation of radioactive substances emited by the active medical devices;

f) risks associated with leakage or release of the medicinal product which is an integral part of the medical device;

g) dangers that may occur when it is not possible to maintain or calibrate, including: reduced isolation of electric power, the aging of the used materials, excess heat generated by the active medical device for implantation, reduced fluid of any measurement or control system and the like.

Article 52

(1) If a medical device is in accordance with BiH standards that are accepted and in compliance with European standards, it shall be considered that it is in compliance with the appropriate specific requirements.

(2) A reference to standards including the monographs of the European Pharmacopoeia, which are specifically related to surgical suture, as well as interactions between medicines and materials that form the components of products containing these medicines.

(3) If it is determined that a medical device that is set up correctly and used for its intended use, may compromise the health and safety of patients, users or other persons, the Agency shall withdraw this medical device from the market or restrict its use to ex officio or upon request of inspectors in the field of medical devices.

(4) When a medical device that does not meet the specific requirements has the mark of conformity, the Agency shall withdraw this medical device from the market on the notification from the inspector in the field of medical devices.

Article 53

(Labeling of medical devices and instructions for use)

(1) Every medical device that is marketed in Bosnia and Herzegovina should be labeled as such on the outer and the immediate packaging in one of the official languages in BiH and have attached instructions for use.

(2) The labeling of medical devices means specifying information about medical devices on the outer or immediate packaging.

(3) Information required for the safe use of medical devices should be listed on the medical device, or where possible, on the packaging for each unit.

(4) If it is not practicable for each unit of the packaging, information shall be included in the instructions for use for each unit or medical device and attached in the package.

(5) Exceptionally, instruction is not necessary for the medical device of class I and IIa, if the same may be used safely without instructions. Instruction is not required for medical devices which are handled by the professional staff.

(6) Information about the medical devices may be provided in the form of symbols or identification colors, in accordance with the general regulations and accepted standards.

(7) Where there are no standards, symbols and identification colors should be described in the documentation accompanying the request for determination of compliance of medical devices and the instructions for use of medical devices.

Article 54

On the primary packaging (envelope) of the medical device or on the sales packaging, there shall be indicated the following information:
a) the name and address of the manufacturer or importer / distributor;
b) the name and information about the medical device and its purpose;
c) batch number and date of manufacture;
d) the expiry date (year, month);
e) for sterile medical devices, the words "sterile", with reference to a method of sterilization;
f) for disposable medical devices, text: "for single use";
g) for custom made medical devices, text: " custom made";

h) for medical devices intended for clinical trial text: 'intended exclusively for clinical trials ";

i) for medical devices intended for scientific research and development text: 'intended exclusively for scientific research and development ";
j) storage conditions, storage and handling of the medical device;
k) on security measures during transport, storage and use;

l) the batch number of the medical device for parts of the of the medical device that may be removed;

m) in case that the intended use is not obvious to the user, it should be clearly indicated on the packaging and in the instructions for use of the medical device.

Article 55

(1) The instructions for use should be written in one of the official languages in Bosnia and Herzegovina, in an understandable manner, to allow the user the proper and safe use.

(2) Instructions for use of the medical devices shall contain:
a) information listed in "Article 42 of the Ordinance", except for the number of series and shelf life;
b) information on the activities of the medical device and the side effects;

c) information about the properties and behavior of the medical device when used in combination with other medical devices or equipment;
d) the measures necessary for the efficient and safe operation;
e) the information about calibration and maintenance for the safety of operation;
f) the information necessary for effective and safe implantation of a medical device;

g) information about the risk with regard to mutual action of medical devices during testing, use or treatment;
h) the necessary instructions for the case of damage to the packaging of sterile medical devices and instructions on ways and methods of re-sterilization;

i) in repeated use, methods which allow reuse, including cleaning, disinfection, packaging and, if necessary, re-sterilization, the method of sterilization of a medical device, meeting the general and specific requirements;

j) if they are intended to be reusable, all restrictions on the number of re-use or sterilization;

k) medical devices that radiate ionizing rays, or release energy, information on the nature, type, intensity and distribution of radiation or energy.

Article 56

Instructions for use of medical devices, in addition to information from the "Article 43 of this Ordinance," should contain information on contraindications and the necessary security measures, including:
a) security measures in the case of changes or weakening of effects of medical devices;

b) security measures that are necessary considering the environment, and exposure to a magnetic field, electrical influences, electrostatic discharge, change in pressure, acceleration, heat source, and the like;

c) safety measures for medicinal products or other devices, which are provided by the designed medical devices;

d) safety measures that are necessary for the safe and effective removal of medical devices;

e) safety measures for medicinal products that are an integral part of medical devices, their release, in accordance with subparagraph d) of this Article;

f) security measures on these levels of accuracy for products with a measuring function.

CHAPTER III - MARK AND DECLARATION OF CONFORMITY

Article 57

(1) The manufacturer shall ensure the use of quality assurance system approved for the design, production and final testing of medical devices. The declaration of conformity is the procedure whereby the manufacturer ensures and declares that medical devices satisfy the provisions of this Ordinance.

(2) The Agency accepts all certificates on the quality of the original or a certified translation issued by the authorities verified for verification of compliance of medical devices with the directives and regulations of the European Union (CE).

(3) If the manufacturer does not have a certificate of compliance of the quality with EU directives and regulations, it should apply to the Agency for determination of compliance. The application shall include the following information:

a) the name and address of the manufacturer and all other production sites that require the same quality system;

b) all relevant information about medical devices or types of medical devices that are subject to evaluation;

c) the quality system documentation, which is applied at all stages of production of medical devices;
d) a statement by the manufacturer that it shall maintain the status and effectiveness of the approved quality system;

e) a statement by the manufacturer that it would monitor the scientific and technical developments and experiences in the field of medical devices and introduce procedures for improving them.

(4) besides the application, one shall prepare the technical documentation that should enable the conformity of the medical device, which contains the following information:

a) a general list of medical devices, design specifications, including standards that are used and the result of the risk analysis;

b) plan's design, description of production processes, description of components and auxiliary parts of the medical device;

c) the responsibility of leading personnel and its competencies during the development of a medical device;
d) methods of monitoring of applied quality system;

e) a description of the methods of sterilization in the case of sterile products and test results;

f) proof that the medical device meets the essential requirements in the case when it is connected to other medical product with the characteristics specified by the manufacturer;

g) clinical data when required in accordance with this Ordinance;
h) labeling and instructions for use.

(5) The certificate of compliance shall contain conclusions of the examination of documents and grounded review.

(6) Costs related to the issuance of the certificate of conformity shall be borne by the manufacturer of the medical device.

Article 58

(1) The Agency should, through the competent committee establish a quality system and examine whether the quality assurance systems are in accordance with accepted standards.

(2) The Committee for determination of compliance should have at least one member with experience in assessing the technological process. The composition of the committee is nominated by the entity`s ministers of health.

(3) In the process of adoption of the certificate of compliance of a particular type of a medical device, the Agency may seek the opinion of the authorized institutions on the territory of Bosnia and Herzegovina.

(4) The Agency, based on the expert opinion of the competent committee, shall issue a certificate of compliance which includes:

a) administrative information about the medical device;
b) a statement of compliance of the medical device;
c) a test report and professional medical opinion on medical devices;
d) certificate or other document of compliance.

Article 59

(1) For medical devices of Class IIa, IIb and III and products lists A and B "referred to in Article 5 of this Ordinance," which does not possess a certificate of compliance in accordance with the directives and regulations of the European Union (CE), the compliance of the product is determined under the terms of to this Ordinance and the Act.

(2) For Class I medical devices manufacturer himself determines the compliance of its medical devices with prescribed requirements and provides a Statement of Compliance on its own responsibility, except for sterile medical devices class I and medical devices which have a measuring function, which are treated as medical devices of higher classes.

(3) Statement of Compliance ensures the full implementation of quality assurance system of the medical device.

(4) The manufacturer shall ensure the use of quality systems in the production and control of the finished medical devices, and the verification of the same, "in accordance with Article 46 of this Ordinance."

Article 60

The certificate of compliance in terms of use, nature of action and the application of medical devices should be based on all the information obtained in clinical trials, especially when it comes to implantable medical devices and Class III, as well as data from the scientific literature on the purpose and use of medical devices and techniques used in their production.

Article 61

(1) Medical devices if they fulfill the basic requirements of this Ordinance, before they are put on the market shall be marked with the mark of compliance.

(2) Medical devices which have a certificate of compliance and mark of compliance provided in accordance with the directives and regulations of the European Union may be placed on the market if they are registered in the Register of the Agency.

(3) Medical devices that are clinically tested or produced on order for a particular user are not marked with the prescribed mark.

(4) Medical devices which do not have a mark of conformity issued by the competent authorities of the European Union may be put into circulation on the basis of a certificate of compliance issued by the Agency and entry into the Registry of the Agency.

Article 62

(1) The system of quality assurance should cover all phases of the production of medical devices, from design to control of the finished medical devices, labeling, storage and distribution.

(2) In terms of the monitoring of the quality system, there should be developed methods and procedures for effective monitoring of the quality system and its application in all stages of production, particularly for sterile medical devices, methods of sterilization and packaging, and labeling of the same.

(3) The Agency shall periodically control the implementation of the approved quality system to determine that the manufacturer adheres to the approved quality system, maintains it and works to improve it.

(4) The Agency may perform unannounced control of the manufacturer and conformity assessment, and if necessary, may conduct or ask for tests in order to verify that a quality system works, where the manufacturer should submit a test report which was carried out with reports.

Article 63

(1) Changes to the quality system should be re-approved by the authority which has approved the quality system or authority for determining compliance.

(2) The manufacturer shall inform the body which approved the quality system or the body for determining compliance that issed the certificate of compliance of any changes and deviations from the approved quality system.
(3) The Agency shall decide on the acceptance of the approved quality system and its assessment.

PART VIII - CATEGORIES OF MEDICAL DEVICES

Article 64

(1) Every medical device should be classified in only one category.

(2) Classification of medical devices in the category is done by starting with the upper category and it continues downward as indicated in the table.

(3) The categories of medical devices, with label of the code are presented in the table below with arranged series from 01 to 13 according to the degree of risk and method of application.

CODE	Description of categories of medical devices
01	Active surgical implants
02	Anaesthetic and respiratory medical devices
03	Dental Medical Devices
04	Medical electro-mechanical devices
05	Hospital hardware
06	"In vitro" diagnostic medical devices
07	Non-active surgical implants
08	Ophthalmic and optical medical devices
9	Reusable instruments
10	Disposable instruments
11	Technical aids for disabled persons
12	Diagnostic and therapeutic medical devices in radiology
13	Other medical devices

PART NINE-CONDITIONS FOR REGISTRATION INTO THE REGISTER OF MEDICAL DEVICES

Article 65

(1) The Agency shall keep the register of the manufacturers and legal persons engaged in wholesale trade of medical devices as well as the register of medical devices that are in circulation in BiH.

(2) The Expert Council on the recommendation of the Director prescribes the content of the register of manufacturers and legal persons engaged in wholesale trade of medical devices, as well as the Register of medical devices that are in circulation in BiH, and the availability of the Register.

(3) The Minister of Civil Affairs on the proposal of the Expert Council shall prescribe the content of documents and the application process of production and wholesale transport of medical devices and the process of their verification. The amount of the costs of entry in the Register of legal entities which perform production activities and wholesale distribution, and medical device registration in the Register shall be prescribed by the Council of Ministers on the recommendation of the Director.

(4) The entry of a medical device in the Register is the administrative procedure conducted by the Agency for the purpose of records of medical devices on the market in BiH, and to protect public health.

(5) An application for registration of medical devices is submitted by the manufacturer of medical devices based in BiH or legal person representing a foreign manufacturer and which has its headquarters in Bosnia and Herzegovina

(6) A representative of the manufacturer is obliged to have the authorization provided by the manufacturer or distributor contract, registered with the Ministry of Foreign Trade and Economic Relations BiH.

(7) The manufacturer or authorized representative shall submit complete information on the insurance of manufacturers` responsibility for possible damage caused to the user of a medical device that is valid on the territory of Bosnia and Herzegovina.

(8) By entry of medical devices in the Register, the applicant is entitled to their placing on the market of Bosnia and Herzegovina.

(9) On the registration of a medical device in the Register of medical devices, the Agency decides by a certificate registered in the Register, which it is required to issue within 90 days from receipt of a complete application. One may not appeal against this certificate, but may file an administrative dispute.

(10) The manufacturers, distributors and medical institutions are required to report to the Agency any observed undesirable or harmful effects caused by medical devices in accordance with the conditions of this Ordinance and the Act.

Article 66

(1) The Agency shall consider only formally complete applications.
(2) Formally complete application includes:

a) filled in a special application form for registration of medical devices in the Register of a corresponding class together with the form Annex 1;

b) complete documentation prescribed for obtaining the certificate on registeration in the Register of medical devices.

(3) If the application is not complete, the Agency shall designate in writing the applicant to amend the same within the set deadline.

(4) If the applicant does not complete the application within this period, the Agency shall reject the application by a conclusion.

Article 67

(1) The applications with the complete documentation are processed by the Committee for Medical Devices, which on the basis of expert opinion classifies and determines whether a medical device meets the conditions and requirements of this Ordinance and the Act, and the Director of the Agency proposes registration in the Register medical devices for which have been found:

a) to which category of medical devices belongs medical device that is produced;

b) whether the medical device or attached test sample is manufactured in accordance with the attached documentation;

c) whether the quality system is secured at all stages of production, storage and distribution of

medical devices;

d) whether its efficiency and safety is ensured in accordance with the prescribed conditions of use;

e) whether the security is provided for the other person, or persons handling medical device in accordance with regulatory or other conditions of use;

f) whether the manufacturer in the production process applied the approved quality system, conducted tests that are needed to confirm the application of the approved quality system and how often;

g) whether the action of a medical device is in accordance with the above;
h) whether the relationship between the benefits and risks is in accordance with the above;

i) whether the sterile medical device is ensured sterility in the indicated shelf life;

j) whether it meets the requirements for the marketing of medical devices.

(2) Documents received by the Agency and all data related to medical devices, except for the data entered in the registers of the Agency, constitute a trade secret.

(3) The provisions of the preceding paragraph shall not apply to the exchange of information and warnings between other countries and the competent authorities

Article 68

(1) Besides the application for registration of medical devices of Class I, IIa, IIb and III in the Register, it is necessary to submit the following documents:

a) the application form for the registration in a Register of medical devices of the appropriate class (REG-MD-CL), signed and certified by the applicant, together with the form Annex 1;

b) proof of authorized representation of manufacturers on the territory of Bosnia and Herzegovina, original or certified copy (representation contract or letter of authorization);

c) certificate of compliance of medical devices with the directives and regulations of the European Union (certificate of CE mark, EC certificate) or a certificate of compliance of medical devices, except for medical devices of Class I, the original or a certified copy in the country of origin;

d) a statement from the manufacturer indicating the compliance with the European directive for medical devices with exactly specified class which region a medical device (Declaration of conformity), which refers to the relevant class of medical devices, original or certified copy in the country of origin;

e) proof that the medical device is marketed in the country of manufacturer or one of the countries of the European Union;

f) insurance policy as a proof of insurance of the users from the damage incurred in the application of medical devices;
g) certification of the quality system, except for medical devices of class I;

h) a certificate of conformity of sterile products for sterile medical devices;
i) description of the method of sterilization and tests for sterility control for sterile medical devices;
j) information on medical device (composition, a brief description of the product declared purposes);
k) details of the proposed shelf life and storage conditions;
l) packing, form, material and composition (see attached sample or packaging);

m) instructions for use in a foreign language for products of foreign origin and proposal instructions in one of the official languages in Bosnia and Herzegovina;
n) confirmation of measuring compliance for medical devices with a measuring function;
o) the proof of payment of Agency`s fees for the registration in a Register of medical devices;
p) proof of payment of administrative fees.

(2) The documentation prepared for obtaining the certificate of registration of medical devices in the Register should be neatly arranged according to the order specified in the binders, and at the request of the Agency it is necessary to submit documentation to the members of the Committee in accordance with the Rules of Procedure.

Article 69

(1) Besides the application for registration of in vitro diagnostic medical devices in the Register of Medical Devices is required to submit the following documentation:

a) the application form for registration in the Register of in vitro medical devices (REG-IV-MD), signed and certified by the applicant, together with a sample of Annex 1;

a) the application form for registration in the Register of medical devices of the appropriate class (REG-MD-CL), signed and certified by the applicant, together with the form Annex 1;

b) proof of authorized representation of manufacturers on the territory of Bosnia and Herzegovina, original or certified copy (representation contract or letter of authorization);

c) certificate of compliance of medical devices with the directives and regulations of the European Union (certificate of CE mark, EC certificate) or a certificate of compliance of medical devices, except for medical devices of Class I, the original or a certified copy in the country of origin;

d) a statement from the manufacturer indicating the compliance with the European directive for medical devices with exactly specified class which region a medical device (Declaration of conformity), which refers to the relevant class of medical devices, original or certified copy in the country of origin;

e) proof that the medical device is marketed in the country of manufacturer or one of the countries of the European Union;

f) insurance policy as a proof of insurance of the users from the damage incurred in the application of medical devices;
g) certification of the quality system, except for medical devices of class I;

h) a certificate of conformity of sterile products for sterile medical devices;
i) description of the method of sterilization and tests for sterility control for sterile medical devices;
j) information on medical device (composition, a brief description of the product declared purposes);
k) details of the proposed shelf life and storage conditions;
l) packing, form, material and composition (see attached sample or packaging);

m) instructions for use in a foreign language for products of foreign origin and proposal instructions in one of the official languages in Bosnia and Herzegovina;
n) confirmation of measuring compliance for medical devices with a measuring function;
o) the proof of payment of Agency`s fees for the registration in a Register of medical devices;
p) proof of payment of administrative fees.

(2) The documentation prepared for obtaining the certificate of registration of medical devices in the Register should be neatly arranged according to the order specified in the binders, and at the request of the Agency it is necessary to submit documentation to the members of the Committee in accordance with the Rules of Procedure.

(3) Costs related to the application and registration of medical devices in the Register of medical devices shall be borne by the applicant.

Article 70

(1) By confirming of the Agency for the registration of medical devices in the Register the applicant is entitled to place a medical device on the market until the expiration of the confirmation.

(2) The period of issuance of the certificate on registration of medical devices is five years from the date of issuance of the certificate on the registration in the Register of medical devices.

(3) The entry in the Register shall renew within 30 days the validity of certificates and other documents which have validity period.

(4) The manufacturers or representatives of the manufacturer who submit a certificate which has indicated only the date of issuance, are required to submit a new certificate to the Agency within five years from the date of issuance.

(5) In the event that the validity of expired documents has not been renewed and that they have not been submitted to the Agency within the prescribed time limit, the Agency shall deleted the medical device from the Register by conclusion.

Article 71

(1) During the period of validity of the certificate on the registration in a Register of medical devices, the certificate holder shall inform the Agency in writing of any change, renewal or amendments to certificates issued or submitted documents.

(2) One can apply for one or more amendments of the certificates for registration of medical devices, or for the modification of the submitted documentation.
(3) The holder of the certificate applies for the following changes:

a) change of name and / or address of manufacturer of a medical device;
b) change of name and / or address of the holder of the certificate for the registration of medical devices;
c) change of the holder of certificates for registration of medical devices;
d) change of the titles of medical devices;
e) change of manufacturers of medical devices;
f) changes, repeal or addition of a new place of manufacture of the product specified in the certificate;
g) changes in test procedure of the finished product (alteration of standards and methods);
h) change of appearance and ways of labeling the outer and / or immediate packaging;
i) amendment of forms, packaging or dimensions of medical devices;
j) change of the class of the medical device;
k) change of the period of use of a medical device;
l) change of conditions of storage of medical devices;
m) change in the method and place of issuance of the medical device;
n) other changes.

(4) These amendments should meet general and special requirements in accordance with this Ordinance.

Article 72

With the application for renewal of registration of medical devices in the Register of Medical Devices should be submitted the following documentation:

a) the application form for the registration in a Register of medical devices of the appropriate class with a note that it is renewal of registration, signed and stamped by the applicant, together with the form Annex 1;
c) certificates which expired;
d) proof of payment of costs for re-registration in the Register of medical devices;
e) the proof of payment of administrative fees;
f) a copy of the previously issued decision / certificate.

Article 73

(1) Besides the application for the classification of medical devices in the Register of medical devices one should submitt the following documentation:

a) a request for categorization, signed and stamped by the applicant, together with the form Annex 1 with the correct list of all the devices that are the subject of categorization;

b) a description and the intended use of all devices which are the subject of categorization;
c) a statement by the manufacturer of compliance for all stated devices;
d) proof of payment for categorization;
e) proof of payment of administrative fees.

(2) Other possible documentation necessary for solving individual requirements determined by the Commission, the Agency shall inform the applicant.

(3) The Agency shall pass a decision on the categorization to which one may not appeal, but may file an administrative dispute.

Article 74

The Agency at the request issues expert opinions and answers to queries that have the limited period of one year from the date of issuance.

PART TEN – Trade of medical devices

Article 75

(1) Wholesale trade of medical devices includes procurement, storage, transportation and sale of medical devices, including import and export.

(2) There is a prohibition of the circulation of medical devices that are not compliant with the prescribed general and special requirements of the Law on Technical Requirements for Rroducts and Conformity Assessment, of the Act and regulations made under the Act, or trade of medical devices that are not included in the Register of medical devices conducted by the Agency.

Article 76

Legal entity that operates a wholesale trade of medical devices, apart from the general legal requirements, should meet specific requirements established by law, and shall:

a) before the start of wholesale trade of medical devices, report its activities to the Agency, which is considering the application and keeps the register of legal entities engaged in wholesale trade of medical devices;

b) carry out activities in compliance with good practices and public health protection in accordance with the Ordinance on good distribution-wholesale practice;

c) introduce an insurance of the quality system in the facility of the wholesale of medical devices, which is proven by the relevant "ISO" certificate of quality system issued by the competent certifying house in Bosnia and Herzegovina;

d) have employed a responsible person for the wholesale distribution of medical devices with at least VI level of education of medical, pharmaceutical, dental or other medical orientation, with specialization exam and appropriate education in the field of medical devices, and other professions depending on the nature, purpose, use and class of medical devices;

e) have employed a responsible person with at least VI level of education of medical profession for tracking and reporting of adverse reactions during the application of medical devices and respond to them;

f) provide adequate space, installations and equipment, while ensuring proper storage and distribution of medical devices;

g) maintain proper records of the types and amounts of medical devices, as well as classes, and thus enable the competent authority a record of medical devices in accordance with good distribution-wholesale practice.

Article 77

(1) wholesale trade of medical devices may be performed by:

a) legal entities which have a certificate of registration in the Register of wholesalers of medical devices, issued by the Agency (the wholesale of medical devices);

b) manufacturers of medical devices based in Bosnia and Herzegovina for those medical devices and products that are registered in the Register of medical devices.

(2) Wholesalers may purchase medical devices directly from the manufacturers of medical devices, importers and other wholesalers.

(3) Wholesalers of medical devices, in addition to general legal requirements, shall also meet the special requirements regarding space, equipment and staff.

(4) The necessary premises for the smooth operation are:
• room for receipt of medical supplies;
• room for storage and dispensing of medical supplies according to the types and volume of traffic, as well as their storage in accordance with the declared conditions of the manufacturer;
• room for storage of medical supplies, which are withdrawn from circulation and storage of packaging;
• sanitary facilities;
• space for wardrobe or closet;
• office.

(5) Rooms in the preceding paragraph shall meet the following requirements:

a) that are located on the premises of solid material which is connected to the municipal infrastructure (water, sewage, electricity and telephone network etc ..);

b) that they are functionally connected to the whole for the smooth running of the work process;

c) that the walls, floors and ceilings are made in a way that allows efficient cleaning, disinfection and hygienic care, or that are smooth and made of solid material;

d) that the premises are provided with adequate lighting, ventilation, air conditioning, heating and current hot water.

(6) Wholesalers of medical devices have to provide the necessary equipment for storage of medical devices in accordance with the declared conditions of the manufacturer and the nature and purpose of a medical device.

(7) The requirements for the transport of medical devices in terms of space, equipment and staff are determined by the Agency through the inspection, which is performed by the wholesale inspector of the Agency.

(8) The costs incurred by the procedure referred to in the previous paragraph shall be borne by the applicant for registration in the Register of wholealers of medical devices.

Article 78

(1) The documentation for the registration of legal entities in the Register of wholesalers of medical devices is given in the application form - "Appendix 5 of this Ordinance."

(2) Evidence from the documentation is submitted in the form of originals or certified copies, where the Agency may require the original from the applicant.

(3) Evidence in a foreign language shall be supplied in the form of a certified translation into one of the official languages in use in Bosnia and Herzegovina.

(4) The Agency shall consider only complete applications. The applications are complete if they are made in accordance with provisions "of paragraph 1 of this Article."

(5) For incomplete application, the Agency shall give the applicant a deadline to supplement

it, and in the event that the applicant does not complete the application within the set deadline, the Agency shall reject the request as formally incomplete.

(6) After a full formal request "GMP" Inspector of the Agency supervises the fulfillment of conditions related to personnel, facilities and equipment and good wholesale practice in wholesale facility, after which the inspector encloses the record on determined conditions under which a certificate of registration in the Register of wholesalers of medical devices is issued or the application is rejected.

(7) The Agency shall, no later than 30 days from receipt of a complete application, issue a certificate of registration in the Register of wholesalers of medical devices and register the applicant in the Register.

(8) Certificate of registration in the Register of wholesalers of medical devices is issued for period of 5 years.

(9) Confirmation from the previous paragraph shall be final in the administrative procedure and one may initiate an administrative dispute before the competent court.

(10) The applicant shall notify the Agency of any change of data related to the registration or a change in the documentation "referred to in paragraph (1) of this Article."

(11) The Agency shall delete legal entities from the register of wholesalers of medical devices in the following cases:

a) the decision of the competent authority that a legal entity is not eligible to carry out activities in accordance with regulations;
b) a written request of the applicant;
c) termination of the legal entity in the cases provided by a special law.

(12) Wholsaler of medical devices, by the registration in the Register of wholesalers of medical devices, acquires the right for the activities of wholesale trade of medical devices.

(13) The costs of issuing the certificate of registration in the Register of wholesalers of medical devices are borne by the applicant.

Article 79

(1) wholesalers and manufacturers of medical devices may sell medical devices to the:
a) end users (hospitals, prisons, etc.);

b) pharmacies and pharmacy depots;
c) specialty shops for the trade of medical devices in retail.

(2) The Agency may by special act designate specific medical devices or category of medical devices, which may be found in retail, except for the cases referred to in "paragraph 1".

(3) The specialty stores and pharmacies may sell only those medical devices which are registered in the Register of medical devices at the Agency.

(4) Medical devices depending on certain conditions in the certificate of registration in the Register of medical devices are issued or sold in pharmacies and specialty shops on prescription or without a prescription.

(5) A person who has the right to prescribe medicinal products and medical devices may not be the owner or co-owner of the pharmacy nor specialized shops "referred to in paragraph (1) of this Article."

Article 80

It is prohibited to transport medical devices and place them on the market:
a) if they do not have a certificate of registration in the Register of Medical Devices issued by the Agency;

b) they are produced by legal entity that is not registered with the Agency in the Register of manufacturers of medical devices;

c) if they do not have appropriate documentation on quality;
d) if they are not designated under the provisions of this Ordinance;

e) if their validity indicated on the packaging has expired or if there is an established defect in terms of the required quality.

Article 81

(Import and Export)

(1) Medical devices which have a certificate of registration in the Register of Medical Devices in Bosnia and Herzegovina may be imported without special consent of the Agency.

(2) The import of medical devices which are not registered in the Register shall be based on the Agency's approval for import.

(3) Applicant for import of medical devices from the previous paragraph may be:

a) legal entities registered in the Register of wholesaler of medical devices managed by the Agency;
b) health facilities;

c) natural persons, if they import medical devices at the proposal of the health institution, for the purpose of individual treatment.

(4) The Agency may require a control of the sample of each imported medical device, if it is in the interests of the health or insurance of the required quality of the medical device.

(5) The costs of issuing the import approval for medical devices "referred to in paragraph (2) of this Article" shall be borne by the applicant.

(6) The export of medical devices is done only with the verification of the application for export without a special procedure of approval of the Agency for the purpose of collecting statistical data on realized exports from Bosnia and Herzegovina.

Article 82

(1) The Agency shall issue the approval for the import of medical devices that are not included in the register in the following cases:

a) if there is an urgent need for the import of medical devices necessary for the operation of hospitals, clinics, clinical center or institute;

b) if there is an urgent need for the import of medical devices necessary for individual treatment, at the proposal of the health institution;
c) if they are intended for scientific research, with the exception of clinical trials.

(2) The import of medical devices from the humanitarian aid and for the purposes of a

clinical trial approved by the competent entities` ministries of Health and the Department of Health of Brcko District.

Article 83

Documentation for the import of the medical device that is not registered in the Register of medical devices shall contain:

a) a completed application form for import of medical devices, which are not included in the register of medical devices, made by the Agency and published to its web site;

b) the invoice of the manufacturer or supplier with all the necessary information about medical devices, packaging, serial number, price and quantity;

c) a statement of justification of import of the medical device and purpose of imports on end-user memorandum, signed by the director of medical or scientific institutions for which the medical device is imported;

d) a certificate of quality of a medical device that is imported, issued by the body authorized to confirm the manufacturer ("EC Certificate and / or Declaration of conformity");

e) proof of payment of the agency's fee for processing the submission and granting approval for the import of medical devices that are not registered in the Register;

f) proof of payment of administrative fees.

Article 84

The customs authorities of the border crossing through which the unregistered medical devices have been imported, shall immediately after the completed import, notify the Agency ie submit a copy of a notarized consent of the customs authority, and for the registered medical devices copy of proof of realized imports.

PART ELEVEN-ADVERTISING OF MEDICAL DEVICES, MATERIO-VIGILANCE AND DISPOSAL OF MEDICAL PRODUCTS OUT OF USE

Article 85

(Advertising)

(1) Reporting about medical devices and advertising are being conducted in accordance with the Ordinance on advertising of medicinal products and medical devices.

(2) The Agency shall inform the scientific community about medical devices which are registerd in the register:

a) publication in the Official Gazette of BiH, FBiH, RS and Brcko District at least once every three months;

b) publication of the Register of medical devices BiH, ensuring the availability of Register to professional public;

c) publication of the database of medical devices.

(3) The Agency and the entities` Ministries of Health and the Department of Health of Brcko District through public media may inform the general public about medical devices or activities being carried out in conjunction with them if required to protect the health of the

population.

Article 86 (Materiovigilanca)

(1) The provisions of Art. 72, paragraph 1 of the Act relating to pharmacovigilance appropriately apply to medical devices and the process materiovigilance.

(2) Side effects of medical devices are regulated by the Ordinance on the method of collecting and monitoring adverse effects of medicinal products and medical devices.

Article 87
(Waste disposal)

(1) Transport of medical devices that are no longer in use or that are defective is not allowed.

(2) Medical devices that are no longer in use shall be disposed of at the expense of the owner or the natural or legal persons that possessed the medical device at the time.

(3) At the disposal of medical devices "referred to in paragraph (1) shall be" consistently applied "the provisions of Articles 93, 94 and 95 of the" Act and the Ordinance, which is adopted in this area, and derives from the said articles of the law.

(4) Medical waste is disposed of in a manner that will not cause a threat to the life and health of people and the environment.

PART TWELVE - FINAL PROVISIONS

Article 88

(1) Legal entities engaged in the production and trade of medical devices, shall have their business and the organization harmonized with the provisions of this Ordinance within 60 days from the date of entry into force of this Ordinance.

(2) The requirements for the issuance of all types of registration in the Register of Medical Devices, submitted before the entry into force of this Ordinance shall be subject to the provisions of this Ordinance.

Article 89

The grammatical terminology of using masculine gender in this Ordinance implies the inclusion of both genders.

Article 90

(1) Amendments to this Ordinance shall be made in a manner of and according to the procedure for its adoption.

Article 91

This Ordinance shall also constitute Appendixes from 1st to 5th.

Article 92

This Ordinance shall enter into force on the eighth day of its publication in the "Official Gazette of BiH", and shall apply until the adoption of regulations on the takeover of the relevant directives of the European Union.

No 08-02-2-1172-1-JD / 09
Date: 10 December 2009

Minister
Mr. Sredoje Novic

Appendix 1

The Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina
Veljka Mla enovića b.b. Banja Luka phone: + 387 0 51 456-040, 456-041,456-050; fax: + 387 0 51 450-301; e-mail: registracija-ms@alims.gov.ba

Number of subject:	Received by:
Date of receipt:	Date of request for additional documentation:
Date of receipt of additional documentation:	Date from when the request is formally complete:

Filled out by Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina

APPLICATION
FOR THE REGISTRATION OF MEDICAL DEVICES Class I
IN THE REGISTER OF MEDICAL DEVICES

(Application is filled out separately for each manufacturer, class and category)

BASIC INFORMATION ON APPLICANT (fill in block letters) 1 **APPLICANT for obtaining certificate for registration of medical device in the Register**		
Full name of the company:		
Address:		
Telephone, fax:		
E-mail:		
Name, surname and occupation of the person responsible:		

INFORMATION ON MANUFACTURER OF MEDICAL DEVICE		
1. Manufacturer in Bosnia and Herzegovina		
Full name of the company:		
Address:		
Telephone, fax:		
E-mail:		
Certificate on registration into Register of manufacturers number:		
List of contracting parties which produced certain parts of medical device for the manufacturer:		
Number of certificate on registration into Register of manufacturers of medical devices:		

2. . Manufacturer outside Bosnia and Herzegovina

Full name of the company: **Country:**	
Address:	
Telephone, fax: **E-mail:**	
Place of production (specify full name of the company and the address from the certificate):	
Certificate of the applied quality system:	
Issued by:	
Number of certificate:	
Valid until:	
Valid proof of registration of medical devices in the register in the country of manufacture:	

Indicate if it is the first registration, amendment or alternation of registration or renewal of registration

☐ First registration

☐ Renewal

☐ Amendment

☐ Alternation

In the case of amendment or alternation, indicate which amendment or alternation is in order (from 1 to 14) and attach the appropriate documentation. Also, specify the number of the certificate by which the medical device is registered in the Register of Medical Devices of Bosnia and Herzegovina.

1.	**Change of name and / or address of manufacturer of the medical device**	
2.	**Change of name and / or address of the holder of the certificate for the registration in the Register of Medical Devices**	☐
3.	**Change of certificate holder for the registration in the Register of Medical Devices**	☐
4.	**Change of name of the medical device**	☐
5.	**Change of manufacturer of the medical device**	☐
6.	**Modification, revocation or addition of a new place of manufacture of the product, stated in the certificate**	☐ ☐
7.	**Change in test procedure of the finished product (alteration of standards and methods)**	☐
8.	**Change of appearance and method of labeling of the outer and / or immediate packaging**	☐
9.	**Amendment or alteration of forms, packaging or dimensions of medical devices**	☐
10.	**Change of class of the medical device**	☐
11.	**Change of expiry date of the medical device**	☐
12.	**Change of storage condiitons of the medical device**	☐
13.	**Change of method and place of issue of the medical device**	☐
14.	**Other changes**	☐

Number of previously issued certificate:

MARK THE STATUS OF THE APPLICANT

☐ **Manufacturer of MD, which has a licence to manufacture in BIH (registered in the registar of manufacturers)**

☐ **Representative of a foreign manufacturer**

☐ **Representative of a foreign manufacturer**

☐ **Legal entity that performs the wholesale distribution (registered in the register of distributors)**

MARK A DIVISION WITHIN THE CLASS OF A MEDICAL DEVICE

☐ **I Class**

☐ **I Class - sterile product**

☐ **I Class - measuring instrument**

Annex - 1

CATEGORIES OF MEDICAL DEVICES

Medical devices shall be classified in only one category. Mark with a cross.

CODE	CATEGORIES OF MEDICAL DEVICES	
01	Active surgical implants	☐
02	Anaesthetic and respiratory medical devices	☐
03	Dental medical devices	☐
04	Medical electro-mechanical devices	☐
05	Hospital hardware	☐
06	"In vitro" diagnostic medical devices	☐
07	Non-active surgical implants	☐
08	Ophthalmic and optical medical devices	☐
09	Reusable instruments	☐
10	Disposable instruments	☐
11	Technical aids for disabled persons	☐
12	Diagnostic and therapeutic medical devices in radiology	☐
13	Other medical devices	☐

INFORMATION ON CERTIFICATES AND COMPETENT BODIES FOR DETERMINATION OF COMPLIANCE

Provide information about the body for determination of conformity which issued a certificate of conformity for the sterilization procedure or the measurement functions of the medical device.

Number of EC-certificate: _____

Name and identification number of the body for determining compliance: _____

Certificate valid untill: _____

STATEMENT OF THE RESPONSIBLE PERSON OF THE APPLICANT

I, the undersigned, claim:

- That the attached registration documentation is credible and that the medical device class l, which is covered by the application for the registration in the Register of Medical Devices, corresponds to the required regulations. I commit myself to immediately report any change in connection with the medical device to the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina,;

- That I shall monitor side effects of medical devices and report them to the relevant authorities in accordance with the regulations;

- That I shall have insight into the registration documentation, which I submit to the Agency;

- That the reported activity is performed so that it provides a protection to public health and in accordance with applicable regulations;

- That I shall renew and submit to the Agency all the certificates which expire. Name, surname and title of the person responsible (director of the company) - printed

Company name:

Signature: Date:

Company stamp:

Name and surname of the responsible of persons for:
- The application of the medical device and authenticity of documents submitted to obtain a certificate of registration of medical devices in the Register;

- Provision of quality of medical devices in accordance with Article 40-44 Ordinance on Medical Devices.

Signature: Date:

Company stamp:

FORM REG-MD-CL IIa, IIb, III

Appendix 2

The Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina
Veljka Mla enovića b.b. Banja Luka phone: + 387 0 51 456-040, 456-041,456-050; fax: + 387 0 51 450-301; e-mail: registracija-ms@alims.gov.ba

Number of subject:	Received by:
Date of receipt:	Date of request for additional documentation:
Date of receipt of additional documentation:	Date from when the request is formally complete:

Filled out by Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina

APPLICATION
FOR THE REGISTRATION OF MEDICAL DEVICES Class IIa, IIb, III
IN THE REGISTER OF MEDICAL DEVICES

(Application is filled out separately for each manufacturer, class and category)

BASIC INFORMATION ON APPLICANT (fill in block letters) 1 **APPLICANT for obtaining certificate for registration of medical device in the Register**		
Full name of the company:		
Address:		
Telephone, fax:		
E-mail:		
Name, surname and occupation of the person responsible:		

INFORMATION ON MANUFACTURER OF MEDICAL DEVICE **1. Manufacturer in Bosnia and Herzegovina**		
Full name of the company:		
Address:		
Telephone, fax:		
E-mail:		
Certificate on registration into Register of manufacturers number:		
List of contracting parties which produced certain parts of medical device for the manufacturer:		
Number of certificate on registration into Register of manufacturers of medical devices:		

2. Manufacturer outside Bosnia and Herzegovina

FORM REG-MD-CL IIa, IIb, III

Full name of the company:	
Country: **Address:**	
Telephone, fax:	
E-mail:	
Place of production (specify full name of the company and the address from the certificate):	
Certificate of the applied quality system:	
Issued by:	
Number of certificate:	
Valid until:	
Valid proof of registration of medical devices in the register in the country of manufacture:	

Indicate if it is the first registration, amendment or alternation of registration or renewal of registration

☐ First registration

☐ Renewal

☐ Amendment

☐ Alternation

In the case of amendment or alternation, indicate which amendment or alternation is in order (from 1 to 14) and attach the appropriate documentation. Also, specify the number of the certificate by which the medical device is registered in the Register of Medical Devices of Bosnia and Herzegovina.

1.	**Change of name and / or address of manufacturer of the medical device**	
2.	**Change of name and / or address of the holder of the certificate for the registration in the Register of Medical Devices**	☐
3.	**Change of certificate holder for the registration in the Register of Medical Devices**	☐
4.	**Change of name of the medical device**	☐
5.	**Change of manufacturer of the medical device**	☐
6.	**Modification, revocation or addition of a new place of manufacture of the product, stated in the certificate**	☐ ☐
7.	**Change in test procedure of the finished product (alteration of standards and methods)**	☐
8.	**Change of appearance and method of labeling of the outer and / or immediate packaging**	☐
9.	**Amendment or alteration of forms, packaging or dimensions of medical devices**	☐
10.	**Change of class of the medical device**	☐
11.	**Change of expiry date of the medical device**	☐
12.	**Change of storage condiitons of the medical device**	☐
13.	**Change of method and place of issue of the medical device**	☐
14.	**Other changes**	☐

Number of previously issued certificate:

MARK THE STATUS OF THE APPLICANT

Manufacturer of MD, which has a licence to manufacture in BIH (registered in the registar of manufacturers)

FOMR REG-MD-CL IIa, IIb, III

☐ **Representative of a foreign manufacturer**

☐ **Representative of a foreign manufacturer**

☐ **Legal entity that performs the wholesale distribution (registered in the register of distributors)**

MARK A DIVISION WITHIN THE CLASS OF A MEDICAL DEVICE

☐ **I Class**

☐ **I Class - sterile product**

☐ **I Class - measuring instrument**

Annex - 1

CATEGORIES OF MEDICAL DEVICES

Medical devices shall be classified in only one category. Mark with a cross.

CODE	CATEGORIES OF MEDICAL DEVICES	
01	Active surgical implants	☐
02	Anaesthetic and respiratory medical devices	☐
03	Dental medical devices	☐
04	Medical electro-mechanical devices	☐
05	Hospital hardware	☐
06	"In vitro" diagnostic medical devices	☐
07	Non-active surgical implants	☐
08	Ophthalmic and optical medical devices	☐
09	Reusable instruments	☐
10	Disposable instruments	☐
11	Technical aids for disabled persons	☐
12	Diagnostic and therapeutic medical devices in radiology	☐
13	Other medical devices	☐

INFORMATION ON CERTIFICATES AND COMPETENT BODIES FOR DETERMINATION OF COMPLIANCE

Provide information about the body for determination of conformity which issued a certificate of conformity for the sterilization procedure or the measurement functions of the medical device.

Number of EC-certificate: _____

Name and identification number of the body for determining compliance:

_____

Certificate valid untill:

FORM REG-MD-CL IIa, IIb, III

STATEMENT OF THE RESPONSIBLE PERSON OF THE APPLICANT

I, the undersigned, claim:

- That the attached registration documentation is credible and that the medical device class l, which is covered by the application for the registration in the Register of Medical Devices, corresponds to the required regulations. I commit myself to immediately report any change in connection with the medical device to the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina,;

- That I shall monitor side effects of medical devices and report them to the relevant authorities in accordance with the regulations;

- That I shall have insight into the registration documentation, which I submit to the Agency;

- That the reported activity is performed so that it provides a protection to public health and in accordance with applicable regulations;

- That I shall renew and submit to the Agency all the certificates which expire. Name, surname and title of the person responsible (director of the company) - printed

Company name:

Signature: Date:

Company stamp:

Name and surname of the responsible of persons for:
- The application of the medical device and authenticity of documents submitted to obtain a certificate of registration of medical devices in the Register;

- Provision of quality of medical devices in accordance with Article 40-44 of the Ordinance on Medical Devices.

Signature: Date:

Company stamp:

FORM REG-IV-MD **Appendix 3**

The Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina
Veljka Mla enovića b.b. Banja Luka phone: + 387 0 51 456-040, 456-041,456-050; fax: + 387 0 51 450-301; e-mail: registracija-ms@alims.gov.ba

Number of subject:	Received by:
Date of receipt:	Date of request for additional documentation:
Date of receipt of additional documentation:	Date from when the request is formally complete:

Filled out by Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina

APPLICATION
FOR THE REGISTRATION OF *IN VITRO* DIAGNOSTIC MEDICAL DEVICE IN THE REGISTER OF MEDICAL DEVICES

(Application is filled out separately for each manufacturer, class and category)

BASIC INFORMATION ON APPLICANT (fill in block letters) 1 **APPLICANT for obtaining certificate for registration of medical device in the Register**		
Full name of the company:		
Address:		
Telephone, fax:		
E-mail:		
Name, surname and occupation of the person responsible:		

INFORMATION ON MANUFACTURER OF MEDICAL DEVICE **1. Manufacturer in Bosnia and Herzegovina**		
Full name of the company:		
Address:		
Telephone, fax:		
E-mail:		
Certificate on registration into Register of manufacturers number:		
List of contracting parties which produced certain parts of medical device for the manufacturer:		
Number of certificate on registration into Register of manufacturers of medical devices:		

FORM REG-IV-MD

2. Manufacturer outside Bosnia and Herzegovina		
Full name of the company:		
Country: **Address:**		
Telephone, fax:		
E-mail:		
Place of production (specify full name of the company and the address from the certificate):		
Certificate of the applied quality system:		
~~Issued by:~~		
~~Number of certificate:~~		
~~Valid until:~~		
Valid proof of registration of medical devices in the register ~~in the country of manufacture:~~		

Indicate if it is the first registration, amendment or alternation of registration or renewal of registration

☐ First registration

☐ Renewal

☐ Amendment

☐ Alternation

In the case of amendment or alternation, indicate which amendment or alternation is in order (from 1 to 14) and attach the appropriate documentation. Also, specify the number of the certificate by which the medical device is registered in the Register of Medical Devices of Bosnia and Herzegovina.

1.	**Change of name and / or address of manufacturer of the medical device**	
2.	**Change of name and / or address of the holder of the certificate for the registration in the Register of Medical Devices**	
3.	**Change of certificate holder for the registration in the Register of Medical Devices**	
4.	**Change of name of the medical device**	
5.	**Change of manufacturer of the medical device**	
6.	**Modification, revocation or addition of a new place of manufacture of the product, stated in the certificate**	
7.	**Change in test procedure of the finished product (alteration of standards and methods)**	
8.	**Change of appearance and method of labeling of the outer and / or immediate packaging**	
9.	**Amendment or alteration of forms, packaging or dimensions of medical devices**	
10.	**Change of class of the medical device**	
11.	**Change of expiry date of the medical device**	
12.	**Change of storage condiitons of the medical device**	
13.	**Change of method and place of issue of the medical device**	

14. **Other changes**

Number of previously issued certificate:

MARK THE STATUS OF THE APPLICANT

Manufacturer of MD, which has a licence to manufacture in BIH (registered in the registar of manufacturers)
Representative of a foreign manufacturer
Representative of a foreign manufacturer
Legal entity that performs the wholesale distribution (registered in the register of distributors)

MARK A DIVISION WITHIN THE CLASS OF A MEDICAL DEVICE

I Class
I Class - sterile product
I Class - measuring instrument

Annex - 1

CATEGORIES OF MEDICAL DEVICES

Medical devices shall be classified in only one category. Mark with a cross.

CODE	CATEGORIES OF MEDICAL DEVICES	
01	Active surgical implants	
02	Anaesthetic and respiratory medical devices	
03	Dental medical devices	
04	Medical electro-mechanical devices	
05	Hospital hardware	
06	"In vitro" diagnostic medical devices	
07	Non-active surgical implants	
08	Ophthalmic and optical medical devices	
09	Reusable instruments	
10	Disposable instruments	
11	Technical aids for disabled persons	
12	Diagnostic and therapeutic medical devices in radiology	
13	Other medical devices	

INFORMATION ON CERTIFICATES AND COMPETENT BODIES FOR DETERMINATION OF COMPLIANCE

Provide information about the body for determination of conformity which issued a certificate of conformity for the sterilization procedure or the measurement functions of the medical device.

Number of EC-certificate: _____

Name and identification number of the body for determining compliance: _____

Certificate valid untill: _____

FORM REG-IV-MD

STATEMENT OF THE RESPONSIBLE PERSON OF THE APPLICANT

I, the undersigned, claim:

- That the attached registration documentation is credible and that the medical device class l, which is covered by the application for the registration in the Register of Medical Devices, corresponds to the required regulations. I commit myself to immediately report any change in connection with the medical device to the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina,;

- That I shall monitor side effects of medical devices and report them to the relevant authorities in accordance with the regulations;

- That I shall have insight into the registration documentation, which I submit to the Agency;

- That the reported activity is performed so that it provides a protection to public health and in accordance with applicable regulations;

- That I shall renew and submit to the Agency all the certificates which expire. Name, surname and title of the person responsible (director of the company) - printed

Company name:

Signature: Date:

Company stamp:

Name and surname of the responsible of persons for:
- The application of the medical device and authenticity of documents submitted to obtain a certificate of registration of medical devices in the Register;

- Provision of quality of medical devices in accordance with Article 40-44 Ordinance on Medical Devices.

Signature: Date:

Company stamp:

Annex to appendixes 1 - 3

Annex 1

No	Brand name	Generic name	Purpose	Form and packaging (Size, dimensions with all variations)	Catalog number
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

Appendix 4

The Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina
Veljka Mla enovića b.b. Banja Luka phone: + 387 0 51 456-040, 456-041,456-050; fax: + 387 0 51 450-301; e-mail: registracija-ms@alims.gov.ba

Number of subject:	Received by:
Date of receipt:	Date of request for additional documentation:
Date of receipt of additional documentation:	Date from when the request is formally complete:

Filled out by Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina

APPLICATION
FOR ENTRY INTO THE REGISTER OF MANUFACTURERS OF MEDICAL DEVICES

Applicant for a certificate of registration in the register of manufacturers

Full name of the manufacturer:	
Place of production:	
Address:	
Telephone:	
Telefax:	
E-mail:	

CONTENTS OF DOCUMENTATION FOR REGISTRATION OF MANUFACTURERS IN THE REGISTER:

1. Certified copy of the court register with forms 1-4,

2. Certified copy of the decision of the Federal Ministry of Health (if the applicant is from FBiH) or the Ministry of Health and Social Welfare RS (if the applicant is from RS) or

Department of Health of Brcko District (if the applicant is from BD) on fulfillment of conditions relating to staff, space and equipment the manufacturer,

3. Description of the manufacturing process - technological design and documentation of the plan of production,

4. A list of medical devices that are produced,

5. Copy of the insurance policy for damage caused to the user or third party, arising from the

performance of the activity of MD,

6. Evidence of introduced quality system (submit appropriate "ISO" certificate on providing particular system of quality in the manufacturing plant or a copy of the evidence that the proceedings of "ISO" certification were initiated with the relevant house in BiH. If provided with a copy of evidence of the initiated procedure, the applicant is subsequently required, no later than 6 months, to deliver the ultimate, "ISO" certificate).

7. COST OF PROCEDURE
Proof of payment of costs for the procedure for issuing certificates:

Instructions for PAYMENT OF COSTS OF PROCEDURE:
• Paid by: Your Company Name

• Purpose: Payment of costs for issuing a certificate on registration in the register of manufacturers
of medical devices in Bosnia and Herzegovina
• recipient: TSA Treasury BiH
• bank account number (receiver / receiver): 3380002210018390 ("Unicredit bank")
• KM (amount): enter 1000.00 KM
• type of payment: enter "0"
• type of income: 722760

• The number of the taxpayer: thirteen ident. number of legal entity, or JMB of a citizen (for natural persons)

• municipality: headquarters of the payer or the municipality of residence

• Budget Organization: 0717999
• reference number: enter all "0"

8. The proof of payment of administrative fees
INSTRUCTION FOR PAYMENT OF ADMINISTRATIVE FEES:
• paid up: Your Company Name
• Purpose of payment: Payment of fees on request
• recipient: TSA Treasury BiH
• bank account number (receiver / receiver): 3380002210018390 ("Unicredit bank")

• KM (amount): enter 20.00 KM
• type of payment: enter "0"
• type of income: 722903

• The number of the taxpayer: thirteen ident. number of legal entity, or JMB of a citizen (for natural persons)

• municipality: headquarters of the payer or the municipality of residence
• Budget Organization: 9999999
reference number: enter all "0"

Place and date

_____
Applicant

Appendix 5

The Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina
Veljka Mla enovića b.b. Banja Luka phone: + 387 0 51 456-040, 456-041,456-050; fax: + 387 0 51 450-301; e-mail: registracija-ms@alims.gov.ba

Number of subject:	Received by:
Date of receipt:	Date of request for additional documentation:
Date of receipt of additional documentation:	Date from when the request is formally complete:

Filled out by Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina

APPLICATION
FOR ENTRY INTO THE REGISTER OF WHOLESALERS OF MEDICAL DEVICES IN BOSNIA AND HERZEGOVINA

Applicant for a certificate of registration in the register of wholesalers

Full name of the manufacturer:	
Place of production:	
Address:	
Telephone:	
Telefax:	
E-mail:	

CONTENTS OF THE DOCUMENTATION:

1. Certified copy of the court registry, with forms 1-4,

2. A copy of the insurance policy for damage caused to the user or third party, arising from the performance of activities of wholesale trade of MD,

3. Certified copy of proof of ownership (lease) of office space,

4. Certified copy of use permit for business space or appropriate statement,

5. A copy of layout of the wholesale facility, indicating a vertical cross-section,

6. Evidence of introduced quality system (submit appropriate "ISO" certificate on providing particular system of quality in the manufacturing plant or a copy of the evidence that the proceedings of "ISO" certification were initiated with the relevant house in BiH. If provided with a copy of evidence of the initiated procedure, the applicant is subsequently required, no later than 6 months, to deliver the ultimate, "ISO" certificate).

7. Certified copy of evidence of professional qualifications for 2 persons responsible,

8. Certified copy of the employment contract with the responsible person for the wholesale,

9. Proof of payment of costs for the procedure for issuing certificates:

Instructions for PAYMENT OF COSTS OF PROCEDURE:
• paid by: Your Company Name

• Purpose: Payment of costs for issuing a certificate for wholesale of medical devices in BiH

• recipient: TSA Treasury BiH
• bank account number (receiver / receiver): 3380002210018390 ("Unicredit bank")

• KM (amount): enter 700.00 KM
• types of payments: enter "0"
• types of income: 722761

• The number of the taxpayer: thirteen ident. number legal entity, or JMB of a citizen (for natural persons)

• municipality: headquarters of the payer or the municipality of residence
• Budget Organization: 0717999
• reference number: enter all "0"

10. Proof of payment of administrative fees
INSTRUCTION FOR PAYMENT OF ADMINISTRATIVE FEES:
• paid by: Your Company Name
• Purpose of payment: Payment of fees on request

• recipient: TSA Treasury BiH
• bank account number (receiver / receiver): 3380002210018390 ("Unicredit bank")

• KM (amount): enter 20.00 KM
• types of payments: enter "0"
• types of income: 722903

• The number of the taxpayer: thirteen ident. number of legal entity, or JMB of a citizen (for natural persons)

• municipality: headquarters of the payer or the municipality of residence
• Budget Organization: 9999999
reference number: enter all "0"

Place and date

Applicant