

# LAW ON MEDICAL DEVICES

*In force from 12.06.2007*

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## **Chapter one. GENERAL PROVISIONS**

### **Section I. General Provisions**

Art. 1. (1) The present Law shall regulate:

1. the terms and procedures for putting on the market and/or putting into service of medical devices;
2. the obligations of manufacturers, their authorized representatives and those of importers of medical devices;
3. the terms and procedures for issuing authorizations for conformity assessment of medical devices;
4. the terms and procedures for conducting clinical investigations on medical devices;
5. the terms and procedures for wholesale trade in medical devices;
6. the surveillance of the medical devices market;
7. the notification and assessment system regarding incidents/potential incidents related to medical devices.

(2) The purpose of the present Law shall be to ensure the putting on the market and/or putting into service of medical devices which do not threaten life and health of patients, medical experts or third persons when the devices are used according to their purpose and are being stored, distributed, installed, implanted and maintained according to the instructions manufacturers.

Art. 2. (1) Depending on the operation intended by the manufacturer, medical devices shall be categorised as follows:

1. in-vitro diagnostic medical devices;
2. active implantable medical devices;
3. medical devices other than the ones specified in items 1 and 2.

(2) Medical devices under para.1, item 1 are classified in List A, List B and self-testing devices, as well as in other groups determined in the ordinances as per Art.18, depending on the potential risk related to them.

(3) Depending on the potential risk related to them the medical devices under para.1, item 3 are grouped into class I, IIa, IIb and III according to classification rules set out in the ordinances under Art.18.

(4) (amend. – SG 110/08, in force from 21.03.2010) In case the manufacturer and the notified authority determined pursuant to Chapter IV have different opinions regarding the implementation of the classification rules under para.3, the Bulgarian Drug Agency (BDA) shall take a decision. When it deems it appropriate and when the conditions under Art. 6a, item 1 or 2 are present, the BDA shall prepare a justified request to the European Commission for undertaking relevant measures.

(5) (amend. – SG 110/08, in force from 21.03.2010) In case this is explicitly required, the classification rules under para.3 to be brought in compliance with new technologies development and/or with information received according to Chapter VII, BDA shall work out a reasoned request for

undertaking the necessary measures which is to be submitted to the European Commission.

Art. 3. The requirements for medical devices provided for in the present Law also apply to:

1. accessories to the devices;
2. devices including as an integral part a substance which, if used separately, may be considered to be a medicinal product within the meaning of the Law on Medicinal Products in Human Medicine and which has an auxiliary effect on the organism with regards to the principal intended action of the device;
3. devices including as an integral part a substance obtained from human blood or plasma which, if used individually, may be considered a component of a medicinal product or a medicinal product under the Law on Medicinal Products in Human Medicine and which has an auxiliary effect on the organism with regards to the principal intended action of the device;
4. devices with the use of which medicinal products are being applied;

Art. 4. (1) In case certain product comes within the purview of this Law and the ordinance as per Art.7 of the Law for the Technical Requirements for the Products, regarding personal protection devices, introducing Directive EEC 89/686 of the Council, the relevant general safety requirements set out in the ordinance shall apply to the said product.

(2) (In force from 29.12.2009; amend. – SG 110/08, in force from 21.03.2010) In case the medical device comes also within the purview of the ordinance under Art. 7 of the Law for the Technical Requirements for the Products, introducing Directive EU 2006/42 of the European Parliament and of the Council of 17 May 2007 regarding the machines and amending the Directive 95/16/EC and there is a risk of its application, the relevant essential safety requirements set out in it shall apply to it, provided that these requirements are more specific than the ones provided for in the ordinance as per Art.18.

Art. 5. (1) This Law shall not apply to:

1. (suppl. – SG 110/08) medicinal products under the Law on Medicinal Products in Human Medicine. The assessment whether a particular product falls within the scope of application of this law or in the scope of application of the Law on Medicinal Products in Human Medicine shall be carried out on the grounds of the product main purpose of use;
2. medical devices which are an integral part of medicinal products and are intended for single use only in this form by the manufacturer;
3. cosmetic products under the Law of Health;
4. (suppl. – SG 110/08) organs, tissues and cells of human origin intended for transplantation, as well as products containing or obtained from tissues and cells of human origin under the Law of the Transplantation of Organs, Tissues and Cells, except for the medical devices under Art. 3, item 3;
5. organs, tissues and cells of animal origin intended for transplantation, unless a device is manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissue;
6. blood, blood ingredients of human origin within the meaning of the Law on Blood, Blood Donation and Blood Transfusion, as well as devices which incorporate at the time of placing on the market such blood products, plasma or cells, except for medical devices under Art.3, item 3;
7. medical devices under Art.2, para.1, item 1 which are not intended for placing on the market, which are used at the production site and, if used at sites in the immediate vicinity, the ownership on them is not transferred to another legal entity.

(2) In the cases referred to in para.1, item 2 the device must meet the requirements of the Law on Medicinal Products in Human Medicine. The essential requirements provided for by this Law shall be applied only with regards to the particular features referring to the safe operation of the device.

Art. 6. While exercising its powers under this Law, BDA shall:

1. (amend. – SG 110/08) arrange registration under the terms and procedures of Chapter II;
2. issue authorizations for carrying out clinical investigations of medicinal products;
3. issue authorizations or certificates for wholesale trade in medical devices;
4. supervise the medical devices that have been placed on the market and/or put into service;
5. exercise control over the storage, wholesale trade, clinical investigations and safety of medical devices;
6. keep a system for registration and analysis of reports on incidents with medical devices and undertake the necessary measures;
7. have its representatives in the Central Ethics Committee, established under the Law on Medicinal Products in Human Medicine;
8. provide information concerning medical devices that have been placed on the market and/or put into service to the European Database;
9. take part in actions in the medical devices field related to the activity of international authorities, organizations and agreements to which the Republic of Bulgaria is a party, together with the regulatory and control bodies of other countries and the organizations carrying out activity in the sphere of medical devices regulation;
10. (amend. – SG 110/08) create and keep the registers under Art. 31, par. 2, Art. 58, par. 1 and Art. 81;
11. carry out other activities specified in this Law.

Art. 6a (new – SG 110/08, in force from 21.03.2010) The Bulgarian Drug Agency shall draw up a justified request to the European Commission for undertaking necessary measures, whenever it considers, that:

1. the application of the classification rules of Art. 2, par. 3 requires taking a decision for classification of a particular medical device or category of devices of Art. 2, par. 1, item 3;
2. a particular medical device or a group of devices of Art. 2, par. 1, item 3, regardless the classification rules of Art. 2, par. 3 may be classified under a different class of devices;
3. the conformity of a particular medical device or of a group of devices of Art. 2, par. 1, item 2 or 3 must be assessed by applying only one single procedure provided in the ordinances of Art. 18;
4. taking a decision is necessary, whether a particular product or a group of products falls into the scope of application of this law.

Art. 7. (1) For the purpose of registration and issue of registration certificates, issue of authorization and certificates according to this Law, as well as for entering amendments therein, shall be paid fees the amount of which is specified in a tariff, approved by the Council of Ministers.

(2) The amounts of fees under para.1 and of fines and property sanctions enforced on natural and legal persons according to this Law shall be deposited as budget revenue of BDA and the State Agency for Metrological and Technical Control, according to activities carried out by them under para.1.

## **Section II.**

### **Placing on the market and/or putting into service of medical devices**

Art. 8. (1) Medical devices shall be released on the market and/or put into service provided that they meet the requirements of this Law and the acts relating to its implementation.

(2) Medical devices, except for custom-made ones, shall be placed on the market and/or put into service if they bear the CE marking under Art.15 certifying that the compliance of the devices with

the essential requirements has been assessed by means of the applicable conformity assessment procedures.

Art. 9. (1) The Executive Director of BDA shall issue an order for temporary suspension or prohibition of placing on the market and/or putting into service and for withdrawal from the market of medical devices with CE marking as per Art.15, as well as of custom-made devices, which can threaten the health and safety of patients, medical experts or third persons, when they are correctly installed, maintained and used.

(2) The Bulgarian Drug Agency shall notify immediately the European Commission of the order under para.1 and the measures taken, stating the reasons for the medical devices non-conformity with the requirements of this Law and the acts for its implementation, due to:

1. failure to meet the essential requirements referred to in the ordinances as per Art.18;
2. incorrect application of the standards referred to in Art.13, para.1;
3. shortcomings in standards under Art.13, para.1.

Art. 10. (1) The manufacturer is the person in charge of placing on the market and/or putting into service of medical devices.

(2) (amend. – SG 110/08) In case the manufacturer is not established on the territory of a Member State or a state from the European Economic Area, they shall authorize in writing their representative, hereafter referred to as "authorized representative". For a medical device or a device of the same model, launched on the Community market, the manufacturer shall authorize only one person.

Art. 11. (1) Manufacturers of medical devices shall be obliged to design, develop, produce, package and label them according to the essential requirements set out in the ordinances as per Art.18 and to ensure assessment of their conformity by means of applicable procedures.

(2) (amend. – SG 110/08) Conformity assessment under para.1 shall be carried out by the manufacturer.

(3) (new – SG 110/08) The manufacturer may assign to his authorized representative to apply the conformity assessment procedures, laid down in the ordinances of Art. 18.

(4) (prev. par. 3, amend. – SG 110/08) In case the procedures provided for by the ordinances as per Art.18 require the interference of a notified authority under Art.64, para.2, the manufacturer or his/her authorized representative in the cases of par. 3 shall assign the carrying out of the procedures applicable to the device type to a notified authority of their choice within its competence.

(5) (suppl. – SG 110/08) In those cases where medical devices under Art. 2, par. 1, item 3 have been produced utilizing non-viable animal tissue or non-viable product derived from animal tissues, prior to their conformity assessment under para.1 the manufacturer shall carry out risk analysis and management, observing the requirements set out in the ordinances as per Art.18 Art. 18.

(6) (prev. par. 4, amend. – SG 110/08) The manufacturer or his/her authorized representative and the notified authority referred to in para.4 shall enter into an agreement concerning the terms and conditions of performing conformity assessment of medical devices.

Art. 12. (1) (suppl. – SG 41/09, in force from 02.06.2009) As an exception, to the benefit of public health, the Minister of Health or an official authorized by him/her, may authorize the putting into service of a medical device, which does not meet the requirements of Art. 8, upon reasoned request by the Regional Inspectorate for Protection and Control of Public Health (RIPCPH), of the National Centre for Public Health Issues or of a medical establishment and provided that the Executive Director of BDA has expressed a positive opinion.

(2) The terms and procedures for putting into service of medical devices under para.1 shall be determined by an ordinance by the Minister of Health.

Art. 13. (1) Where medical devices have been designed and manufactured according to national standards introducing the harmonized European standards, they shall be presumed to meet the essential requirements determined by the ordinances under Art.18.

(2) (amend. – SG 110/08, in force from 21.03.2010) Where medical devices under Art.2, para.1, item 2 and 3 have been designed and manufactured in conformity with the official pharmacopoeia in the Republic of Bulgaria determined in Art.12 of the Law on Medicinal Products in Human Medicine, they shall be presumed to meet the essential requirements set out in the ordinances as per Art.18.

(3) In case the medical devices referred to in Art.2, para.1, item 1 from List A, and where necessary, from List B, have been designed and manufactured in compliance with general technical specifications, they shall be presumed to meet the essential requirements set out in the ordinances as per Art.18.

(4) In case a manufacturer is unable to observe the requirements under para.3, the latter shall approve technical decisions in order to achieve equivalent results.

(5) In case BDA considers that standards under para.1 do not entirely meet the essential requirements set out in the ordinances as per Art.18, it shall work out and harmonize an official state stand which is to be presented to the European Commission.

Art. 14. (1) Manufacturers of medical devices shall prepare technical documentation the contents of which is determined in the relevant ordinances as per Art.18.

(2) Manufacturers or their authorized representatives shall work out a declaration on the medical devices conformity following implementation of the applicable conformity assessment procedures.

(3) Manufacturers or their authorized representatives shall be obliged to keep available the technical documentation under para.1 and the conformity declaration under para.2 for at least 5 years from the date of the suspension of the medical device manufacture and, upon request, to present to the persons referred to in Art.86, para.2 for inspection.

Art. 15. (1) The CE marking with graphic image according to the Appendix that is affixed on the medical device prior to its placing on the market and/or putting into service must be easy to read and impossible to efface without leaving traces.

(2) The CE marking shall be placed on a visible spot on the device, in the instructions for use and on its sterile packing, if there is such. Where possible, it shall appear on the sales packaging.

(3) The CE marking shall be at least 5 mm high, unless otherwise provided for in the relevant ordinance as per Art.18. If the CE marking size is being decreased or increased, the graphic scale proportions shall be adhered to.

(4) (amend. – SG 110/08) The CE marking shall be accompanied by the identification number placed next to it of the notified body in the cases referred to in Art.11, para.4, where the procedures, contained in the ordinances of Art. 18 require its displaying.

(5) The CE marking and the identification number under para.4 shall not be placed on a device only if the size and form of the device do not allow it.

(6) It is prohibited to affix any other marks on the device, its packing and/or its instructions for which are likely to mislead users – medical experts or patients with regard to the marking under para 1, provided that the visibility and legibility of the CE marking is not thereby reduced.

(7) As regards to devices that are placed on the market in a sterile packing, the CE marking shall be affixed on both the sterile and user packing of the device.

(8) In the case of overall processing of the device which can affect its safe use, the CE marking shall be affixed following a repeated assessment of the device in accordance with the applicable

procedures set out in the ordinances as per Art.18.

(9) Where a medical device falls within the application field of the ordinances as per Art.7 of the Law for the Technical Requirements for the Products subject to CE marking, the marking certifies the compliance of the device with the requirements of each of the ordinances, unless otherwise stipulated therein.

(10) At exhibitions, trade fairs, demonstrations, promotions, scientific and technical conferences can be presented medical devices without affixed CE marking.

(11) In the cases referred to in para.10 manufacturers shall place a visible sign clearly indicating that such devices are not intended for placing on the market and/or putting into service.

Art. 16 (1) Manufacturers of medical devices shall be obliged to specify their name, headquarters and business address on the device, its packing and instructions for use. Instruction for use is not required for devices under Art.2, para.1, item 3 from class I and IIa which, in the manufacturer's opinion can be used safely without instructions for use.

(2) The name and address of the authorized representative and of the importer are additionally specified on the packing and in the instructions for use of devices which are imported from third countries on the territory of the European Union or on the territory of the European Economic Area.

(3) The instruction for use shall also be written in Bulgarian language.

Art. 17. Manufacturers or their authorized representatives shall be obliged to ensure that medical devices are installed in a safe manner on the territory of the Republic of Bulgaria, where necessary due to their specific character according to the instruction for use, and to guarantee their maintenance.

Art. 18. (amend. – SG 82/09, in force from 16.10.2009) Upon proposal by the Minister of Health and the Minister of Economy, Energy and Tourism, the Council of Ministers shall determine by way of ordinance the following issues concerning medical devices referred to in Art.2. para.1:

1. essential requirements;
2. assessment conformity procedures regarding the essential requirements and the contents of the technical documentation;
3. rules for classification of medical devices referred to in Art.2, para.1, item 3;
4. the lists specifying the scope of groups of in-vitro diagnostic medical devices;
5. requirements for carrying out risk analysis and management with regards to medical devices as per Art.11, para.5.

### **Section III.**

#### **Putting on the market and/or putting into service of custom-made medical devices**

Art. 19. (1) (amend. – SG 110/08, in force from 21.03.2010) Prior to placing on the market and/or putting into service of a custom-made medical device under Art.2, para.1, item 2 or 3, the manufacturer or their authorized representative shall prepare documentation containing:

1. the manufacturer's name and address;
2. device identification data;
3. a statement that the device is intended for exclusive use by a particular patient, together with the name of the patient;
4. the name of the medical practitioner or of the dentist who made out the prescription for the device, where applicable, the name of the medical establishment concerned;
5. specific features of the device as specified in the relevant medical prescription

the characteristics of the medical device according to the specification:

6. a statement that the device in question conforms to the essential requirements.

(2) (amend. – SG 110/08, in force from 21.03.2010) In those cases where the device does not meet any of the applicable essential requirements, the non-conformity shall be provided with reasons in the statement under para.1, item 6.

(3) (suppl. – SG 110/08, in force from 21.03.2010) The documentation under para.1 shall be kept by the manufacturer or their authorized representative for a minimum of 5 year-period and in case of implantable medical devices of Art. 2, par. 1, item 3 and of devices of Art. 2, par. 1, item 2 – for a period of minimum 15 years.

(4) (new– SG 110/08, in force from 21.03.2010) The documentation of par. 1, attached to the devices of Art. 2, par. 1, item 2 and the devices of Art. 2, par. 1, item 3 of classes IIa, IIb and III shall be submitted to the particular patient, identified by name, acronym or digital code.

(5) (prev. par. 4, amend. – SG 110/08, in force from 21.03.2010) The manufacturer of custom-made medical devices under Art. 2, para.1, item 2 and 3, shall provide, upon request by BDA, a list of the devices which have been put into service on the territory of the Republic of Bulgaria.

Art. 20. (1) (amend. – SG 110/08) The manufacturer shall prepare documentation including a description of engineering, of production and of the effect of the device, including the expected effect, allowing assessment of product conformity with the requirements of this law and of the provisions of Art. 18. The documentation shall indicate also the address of the production premises.

(2) Manufacturer shall be obliged to take the measures necessary to ensure by production process the conformity of the devices under Art.19 with the documentation as per para.1.

(3) (new – SG 110/08) The manufacturer shall provide the documentation of par. 1 for review upon request by the persons of Art. 86, par. 2.

#### **Section IV.**

#### **Placing on the market of systems or sets of medical devices**

Art. 21. (1) A natural or legal person who makes into sets medical devices referred to in Art. 2, para.1, item 3 with CE marking shall, prior to placing them on the market as a system or set, prepare a declaration stating that:

1. they have completed the system or set according to the purpose of the separate devices and the restrictions on their use determined by the manufacturers;

2. they have checked the conformity of the individual medical devices and have carried out the assembling procedures according to the instructions of manufacturers;

3. they have packed the system or set and they have provided the users with the necessary information including the respective manufacturers' instructions;

4. their activity is subject to internal control and surveillance procedures.

(2) In case any of the requirements of para.1 has not been met, the system or set shall be subject to conformity assessment regarding the essential requirements set out in the ordinances as per Art. 18.

Art. 22. (1) A natural or legal person who sterilizes systems or sets of medical devices as per Art. 21 and/or medical devices referred to in Art. 2, para.1, item 3 with CE marking, which manufacturers have intended for sterilization before use, must assess their conformity by way of procedures set out in the respective ordinance as per Art.18.

(2) (suppl. – SG 110/08) The implementation of the procedures set out in para.1 and the actions of the notified authority shall be restricted to meeting the sterility requirements up to the time of damaging of the integrity of device package.

(3) The person referred to in para.1 shall draw up a declaration in accordance with the requirements set out in the respective ordinance, stating that sterilization has been carried out according to the manufacturers' instructions.

Art. 23. (amend. – SG 110/08) The persons under Art. 21, para.1 and Art. 22, para.1 shall keep the declarations for a period of 5 years and shall present them to the persons referred to in Art. 86, para.2, upon request, in order to be reviewed.

Art. 24. The systems or sets of medical devices under Art. 21, the sterilized systems or sets and the medical devices as per Art. 2, para.1, item 3 with CE marking, intended by the manufacturer for sterilization before use, shall be placed on the market without additional CE marking and shall be accompanied by instructions for use containing, where necessary, the information provided by the manufacturer of the individual devices in the system or set, the requirements for which are determined in the respective ordinance as per Art. 18.

## **Section V. Performance evaluation of in-vitro diagnostic medical devices**

Art. 25. (1) The conformity assessment of in-vitro diagnostic medical devices regarding their specific purpose under conditions of use specified by the manufacturer shall be carried out by way of performance evaluation on the grounds of:

1. collective data from scientific literature relating to the purpose of the device, and a critical analysis of this data, and/or

2. the results from performance evaluation trials or other appropriate tests.

(2) Manufacturers or their authorized representatives, prior to providing in-vitro diagnostic medical devices for performance evaluation to an accredited laboratory, shall prepare documentation containing the following:

1. data allowing identification of the device in question;

2. an evaluation plan stating in particular the purpose, scientific, technical or medical grounds, scope of the evaluation and number of devices concerned

3. a list of accredited laboratories taking part in the evaluation study;

4. the starting date and scheduled duration for the evaluations and, in the case of devices for self-testing, the location and number of lay persons involved;

5. in the case of self-testing devices – location and number of persons who have no medical qualification and will take part in the study;

6. a statement that the device in question conforms to the applicable essential requirements apart from the aspects covered by the evaluation and apart from those specifically itemised in the statement, and that every precaution has been taken to protect the health and safety of the patients, medical experts and other persons.

Art. 26. (1) Manufacturers shall undertake to keep technical documentation as per Art.14, para.1 and shall provide it to the persons referred to in Art. 86, para.2, upon their request, for inspection.

(2) Manufacturers shall be obliged to take all measures necessary for the manufacturing process to ensure the conformity of in-vitro diagnostic medical devices for performance evaluation with the documentation mentioned in para.1.

## **Chapter two.**



## **REGISTRATION OF PERSONS LAUNCHING MEDICAL DEVICES ON THE MARKET (TITLE AMEND. – SG 110/08)**

Art. 27. (1) (amend. – SG 110/08, in force from 21.03.2010) Where manufacturers of medical devices as per Art. 2, para 1, item 3 from class I, manufacturers of custom-made devices under Art. 2, para 1, items 2 and 3, as well as natural or legal persons referred to in Art. 21, para 1 and Art. 22, para 1 are registered under the Commercial Law they shall submit an application for registration to the Executive Director of BDA within 14 days from placing the device on the market and/or putting into service on the territory of the Republic of Bulgaria.

(2) The following documents shall be appended to the registration form under para 1:

1. valid entry certificate in the Commercial register;
2. name and description of the device;
3. document certifying paid fee to the amount fixed in the tariff as per Art. 7, para 1.

(3) (amend. – SG 110/08, in force from 21.03.2010) The persons referred to in para 1 are obliged to notify the Executive Director of BDA of any change in their headquarters address within 14 days. In case of change in the information under para 2, item 2, the bodies under para 1 shall submit an application as per para 1 to the Executive Director of BDA, with documents concerning the change attached to it and a document certifying paid fee to the amount fixed in the tariff as per Art. 7, para 1.

Art. 28. (1) Where a manufacturer of devices referred to in Art. 2, para 1, item 1 places on the market and/or puts into service the said devices on the territory of the Republic of Bulgaria and is registered under the Commercial Law, he/she shall submit an application for registration to the Executive Director of BDA.

(2) The following documents shall be attached to the registration form under para 1:

1. valid entry certificate in the commercial register;
2. information relating to the reagents, reagent products and calibration and control materials in terms of common technological and/or analytical characteristics;
3. in case of devices from list A, list B and self-testing devices - name, type and model of the device, analytical and, if necessary, diagnostic features according to the essential requirements indicated in regulations under Art. 18, results of in-vitro medical device performance evaluation.
4. instruction for use in Bulgarian language;
5. document for paid fee in amount fixed by the tariff as per Art. 7, para 1.

(3) (amend. – SG 110/08) Manufacturers who place on the market and/or put into service a new in-vitro diagnostic medical device within the territory of the Republic of Bulgaria, in case he/they are registered under the Commercial Law, shall submit to BDA the documents set out in para 2 as well as indication that the device is new.

(4) (amend. – SG 110/08) An in-vitro diagnostic medical device is new if on the market of a Member State or a state from the European Economic Area during the last three years:

1. there has been no such device continuously available for the relevant analyte or other parameter, or
2. the analytical technology used in connection with a given analyte or other parameter has not been available.

(5) (revoked – SG 110/08, in force from 21.03.2010).

(6) (amend. – SG 110/08, in force from 21.03.2010) The application form for registration under paras 1 and 3 shall be submitted within 14 days from the date of placing on the market and/or putting into service of devices referred to in Art. 2, para 1, item 1.

(7) (amend. – SG 110/08, in force from 21.03.2010) The persons referred to in paras 1 and 3 are obliged to notify within 14 days the Executive Director of BDA in case of:

1. change in the headquarters address;

2. significant changes in the information as per para 2, items 2 and 3;
3. (revoked – SG 110/08, in force from 21.03.2010);
4. withdrawal of the device from the market.

Art. 29. (amend. – SG 110/08, in force from 21.03.2010) (1) In cases of Art. 10, par. 2 where the authorized representative is registered under the Commercial law, shall submit an application form to BDA with the attached documentation for the devices under Art. 27, par. 1 and/or under Art. 28, par. 1 or 3.

(2) The authorized representative under Art. 1 shall notify BDA about any change of his/her headquarters address.

Art. 30. (amend. – SG 110/08, in force from 21.03.2010) For all devices under Art. 2, par. 1, item 2 and under Art. 2, par. 1, item 3 of classes IIa, IIb or III, put into service in the territory of the Republic of Bulgaria the BDA may request data, identifying the product, label and operation instructions.

Art. 30a. (new. – SG 110/08) (1) The state shall register maximum retail selling prices of medical devices – appliances and equipment in the meaning of § 1, item 21 of the additional provisions.

(2) (amend. – SG 82/09, in force from 16.10.2009) The conditions and the procedure of registration of the prices under par. 1 shall be determined by an ordinance of the Council of Ministers, adopted under a proposal of the Minister of Health and the Minister of Economy, Energy and Tourism.

Art. 31. (1) (revoked – SG 110/08, in force from 21.03.2010).

(2) (amend. – SG 110/08, in force from 21.03.2010) The Bulgarian Drug Agency shall maintain a register containing:

1. number and registration date;
2. name, type and class of the medical device;
3. name and business address of the applicant under Art. 27, par. 1, Art. 28, par. 1 and 3 and Art. 29, par. 1;
4. date of deletion of the medical device from the register and the reason for this;
5. remarks on documented circumstances.

(3) (amend. – SG 110/08, in force from 21.03.2010) The Bulgarian Drug Agency presents registration data for the devices under Art. 27, par. 1, Art. 28, par. 1 and 3 and under Art. 29, par. 1 upon request by the regulatory authorities of other Member States or regulating authorities or the states of the European Economic Area and by the European Commission.

### **Chapter three.**

## **CLINICAL INVESTIGATION OF MEDICAL DEVICES**

### **Section I.**

#### **General Provisions**

Art. 32. (amend. – SG 110/08, in force from 21.03.2010) Clinical testing with medical devices under Art. 2, par. 1, item 2 and 3 shall be carried out in order to:

1. confirm that under normal conditions of use the device performs one or more of its functions, determined by the manufacturer;
2. identify adverse side effects under normal conditions of use of the device;
3. assess to what extent the identified adverse side effects are within the acceptable risk

assessed in comparison to the benefit of the intended purpose of use of the device.

Art. 32a (new – SG 110/08, in force from 21.03.2010) The assessment of clinical testing data shall be carried out under the conditions, set out in the ordinance under Art. 48, par. 2.

Art. 33. A clinical investigation shall be carried out in a medical establishment in accordance with the Law for the Medical Establishments.

Art. 34. (1) Clinical investigations of devices referred to in Art. 32 shall be carried out according to the main principles of the protection of human rights, safety and human dignity of the clinical trial subjects according to the Declaration of Helsinki for the ethical principles of clinical trials with human subjects.

(2) The rights, safety, and health of the subjects in the clinical test shall always prevail over those the interests of science and society.

the interests of the patient always prevail over those of science and society

(3) Clinical investigations shall be initiated and carried out provided that the estimated benefits for the subject and the society justify the risks.

(4) Clinical trials shall be designed to minimise discomfort, pain, fear and any other foreseeable risks in relation to the disease and both the risk threshold and the degree of distress have to be defined in advance and constantly monitored throughout the investigation.

(5) No financial or other incentives shall be given to clinical trial subjects except compensations (travel and daily costs, etc.).

Art. 35. (revoked – SG 110/08, in force from 21.03.2010)

Art. 36. (1) The whole information from a clinical investigation shall be recorded, processed and kept in such a manner as to ensure its precise reporting, interpretation, and confirmation. Personal data of the clinical trial subjects shall be preserved pursuant to the Law for Protection of the Personal Data.

(2) The documentation under para 1 shall be stored by the principal or coordinating investigator for a period of 20 years from the end date of the clinical trial and shall be presented to the relevant Ethics Committee(s) and to BDA upon request.

Art. 37. (1) A clinical trial of the devices referred to in Art. 32 shall only be admitted on a person who:

1. has been provided in advance with written information about the nature, importance, consequences and potential risks of the investigation and has been informed in a prior interview by a doctor or dentist – member of the investigation team, about the objectives, risks and inconveniences of the trial and the conditions under which it is to be conducted;

2. has been informed of his/her right to withdraw from the investigation at any time without this having any negative consequences for him/her;

3. has personally expressed written informed consent to take part in the investigation.

(2) If the individual is unable to write, oral consent in the presence of at least one witness may be given. The witness shall certify in writing that the person has expressed informed consent to take part in the clinical trial in person.

(3) The informed consent pursuant to para 1, item 3, and para 2 can only be given by a capable person who understands the nature, significance, scope, consequences, and potential risks of the clinical trial. Informed consent to participate in a clinical investigation can be withdrawn at any time without negative consequences for the person.

(4) Clinical investigation of partially capable majors shall be carried out after they and their legal representative have expressed written informed consent. A partially capable person shall be provided with information under para 1, item 1 according to his/her capacity of understanding. The explicit wish of the person to be withdrawn at any time is considered by the investigator or, where appropriate, by the principal investigator.

(5) Informed consent of an incapable major person shall be given by his/her legal representative.

(6) In cases referred to in Art. 162, para 3 of the Law for Health, informed consent shall be given by a person assigned by the court.

Art. 38. (1) A clinical trial on a minor person shall be carried out after obtaining written informed consent by his/her legal representatives - both subject's parents or the guardian pursuant to Art. 37, para 1, item 1 and 2 and para 3. Where one of the parents is unknown, deceased, or deprived of parental rights or such rights have not been delegated in case of divorce, written informed consent shall be given by the parent who exercises parental rights.

(2) A clinical trial on an underage person shall be conducted after obtaining written informed consent by the subject and his/her legal representatives - both subject's parents or the guardian according to Art. 37, para 1, item 1 and 2 and para 3. Where one of the parents is unknown, deceased, or deprived of parental rights or such rights have not been delegated in case of divorce, written informed consent shall be expressed by the parent who is exercising parental rights.

(3) Minors or underage persons shall be provided with information about the nature, significance, consequences and eventual risks and benefits of the clinical trial in a manner understandable for that person by a paediatrician or children's psychologist.

(4) The consent of the parents or the guardian must represent the minor's presumed will and may be revoked at any time, without detriment to the minor and/or to them.

(5) The consent of an underage person, his/her parents and guardian can be withdrawn at any time without negative consequences for them.

Art. 39. Where it is not possible to take urgent informed consent by the parent(s) or respectively by the guardian and the direct purpose to save the life of a minor, underage person, incapable or partially capable major, the decision to take part in a clinical investigation of any of the said persons shall be taken by at least two doctors, independent from the assignor and from the principal and coordinating investigator.

Art. 40. (1) Clinical trials on pregnant women can be conducted according to the requirements as per Art. 37 only in those cases where there are no other alternative diagnostics or treatment methods and if it does not threaten the pregnant woman's life and health and the fetus vitality.

(2) Decision for involvement in a clinical investigation in the cases referred to in para 1 shall be taken by a committee of physicians, independent from the assignor and the principal and coordinating investigator.

Art. 41. (1) Subjects shall be provided with further information throughout the clinical investigation by a person independent from the assignor upon request.

(2) The written information provided to the subject during the clinical trial contains contact data of the independent person under para 1.

Art. 42. (1) In those cases where an assignor who is not established on the territory of EU or on the territory of a state from the European Economic Area carries out one-site or multi-centre clinical trial on the territory of the Republic of Bulgaria, the latter shall authorize his/her representative established

on the Republic of Bulgaria.

(2) (amend. – SG 110/08, in force from 21.03.2010) In those cases where an assignor who is not established on the territory of the Republic of Bulgaria and on the territory of another Member State(s) and/or on the territory of a state/states from the European Economic Area and/or on the territory of a third country, he/she shall authorize a representative established on the territory of a state from EU or European Economic Area.

(3) The authorized representative under para 1 and para 2 bears the responsibility for conducting clinical trials on the territory of the Republic of Bulgaria according to the legislation in force.

(4) (revoked – SG 110/08, in force from 21.03.2010).

(5) (revoked – SG 110/08, in force from 21.03.2010).

(6) (revoked – SG 110/08, in force from 21.03.2010).

(7) (revoked – SG 110/08, in force from 21.03.2010).

Art. 43. (amend. – SG 110/08, in force from 21.03.2010) (1) The clinical test shall be carried out under the management of a researcher.

(2) The control over the clinical test shall be carried out by the assignor or by his/her authorized representative under Art. 42, par. 1 or 2 or by an appointed by him/her person-supervisor.

(3) During the clinical test a doctor, respectively a doctor in dental medicine shall follow up the health condition of the participant and, if relevant, he/she shall undertake appropriate medical measures.

(4) The requirements to the assignor, the general or the coordinating researcher and to the supervisor and their obligations during the clinical testing shall be determined by the ordinance of Art. 48, par. 2.

Art. 44. (1) The assignor and principal or coordinating investigator shall conclude insurance agreements, covering their liability for material and non-material damages to the trial subjects.

(2) The assignor shall be responsible in case of damage to health or death caused during or in the occasion of the conduct of the clinical investigation where the said trial has been carried out in compliance with the requirements and procedures of the plan as approved by the ethics committee.

(3) The principal or coordinating investigator shall be responsible in case of health damage or death caused during or in the occasion of clinical trial where the said trial has not been carried out in compliance with the requirements and procedures of the plan as approved by the ethics committee.

## **Section II.**

### **Clinical Trial Authorizations**

Art. 45. (1) Clinical trials of medical devices referred to in Art. 2, para 1, item 3 from class III, of implantable medical devices and invasive medical devices for long-term use as per Art. 2, para 1, item 3 from class IIa or IIb and of devices under Art. 2, para 1, item 2, which take place on the territory of the Republic of Bulgaria can commence upon receiving a positive stand of the Multi-centre Research Ethics Committee or the ethics committee at the respective medical establishment, and an authorization by the Executive Director of the Bulgarian Drug Agency (BDA).

(2) Clinical trials of medical devices other than the ones referred to in para 1 which take place on the territory of the Republic of Bulgaria can commence upon notification to the Executive Director of BDA, if the relevant ethics committee under para 1 has given a favourable opinion.

(3) The provisions of para 1 and para 2 shall also apply to medical devices with applied "CE" marking in case the clinical trials are conducted with the purpose of change in their intended purpose.

Art. 46. The assignor or the principal/coordinating investigator can submit an application form for notification or authorization for conducting a clinical trial to the relevant ethics committee and to BDA simultaneously or consequently.

Art. 47. (1) In the case of multi-centre clinical trial on the territory of the Republic of Bulgaria persons as per Art. 46 shall submit an application form to the Multi-centre Research Ethics Committee.

(2) In the case of one-site clinical trial on the territory of the Republic of Bulgaria persons referred to in Art. 46 shall submit an application form to the Multi-centre Research Ethics Committee or to the ethics committee at the respective medical establishment.

Art. 48. (1) In order to obtain a stand by the relevant ethics committee, the principal, respectively the coordinating investigator or the assigner, shall provide:

1. administrative documentation;
2. information about the subject;
3. documents related to the study plan;
4. documentation on the medical device being investigated;
5. documents related to the technical specifications of the medical establishment and qualifications of the personnel;
6. information about the financing source and trial administrative organization.

(2) The contents of documentation under para 1 is determined in an ordinance of the Minister of Health.

(3) Where the ethics committee establishes that documentation under para 1 is incomplete it shall notify the applicant within 14 days and shall fix a deadline for completing the documentation.

(4) Within 30 days after submission of the valid documentation the ethics committee passes a stand which shall be presented to the applicant and BDA.

Art. 49. (1) If the opinion of the ethics committee as per Art. 48 is negative, the applicant can appeal before the Central Ethics Committee established under the Law on Medicinal Products in Human Medicine within 14 days from the date of notification.

(2) The Central Ethics Committee passes a stand within 14 days from the receipt date of the written request by the applicant.

(3) The decision of the Central Ethics Committee shall be final and binding on the respective ethics committee.

Art. 50. (1) (amend. – SG 110/08, in force from 21.03.2010) In order to get an authorization to conduct clinical test as per Art. 45, para 1, the applicant shall submit an application form to BDA with the following documentation attached:

1. identification data of the medical device on paper and electronic medium;
2. plan of clinical test;
3. researcher's brochure;
4. documentation for obtaining of an informed consent;
5. manufacturer's declaration whether the respective device may be determined as a device under Art. 3, item 2, 3 or 4;
6. manufacturer's declaration whether for the production of the device under Art. 2, par. 1, item 3 non-viable animal tissue or non-viable products, produced from animal tissues, have been used;
7. the names of the researchers, of the general researcher or researchers or of the coordinating researcher, as well as the name and the address of the medical establishments, where the clinical testing is being carried out;
8. starting, closing date and schedule of the implemented tests;

9. positive reference of the ethics commission, where the applicant has submitted subsequent applications under Art. 46;

10. a declaration, that the medical device conforms with the applicable essential requirements, except those, which are subject to clinical testing, and that all preventive measures, required for protection of the health and safety of the participants in the testing and of the research team have been provided;

11. an insurance contract, covering the researcher's and the applicant's responsibility for caused proprietary and non-proprietary damages to the participants in the testing during or with reference to the implementation of the clinical testing;

12. a draft contract between the applicant and the medical establishment;

13. a document certifying paid fee to the amount determined in the tariff as per Art.7, para 1;  
(2) (revoked – SG 110/08, in force from 21.03.2010).

(3) (amend. – SG 110/08, in force from 21.03.2010) In case of application forms as per Art. 46 submitted simultaneously, the applicant can present his/her opinion under para 1, item 9 after its obtaining, but not later than the term fixed under Art. 51, para 1.

(4) (amend. – SG 110/08, in force from 21.03.2010) The applicant shall declare that the information, provided in the documents submitted to BDA and to the ethics commission is identical.

(5) (new – SG 110/08, in force from 21.03.2010) The content of the documentation of par. 1 shall be determined by the ordinance of Art. 48, par. 2.

Art. 51. (1) The Bulgarian Drug Agency assesses the provided documents as per Art. 50 within 60-days from the date of their submission.

(2) (amend. – SG 110/08, in force from 21.03.2010) The Bulgarian Drug Agency may request additional information about the documents referred to in Art. 50, para 1.

(3) In the cases referred to in para 2, the 60-day term shall stop running until the submission of the requested documentation.

(4) Within the period under para 1, the Executive Director of BDA shall notify in writing the applicant that:

1. they issue an authorization to conduct the clinical trial or,
2. the trial may not be carried out, stating the reasons for refusal.

(5) In the cases referred to in para 4, item 2, within 30 days from the date of notification, the applicant can submit to BDA an application amended in accordance with the reasons stated for refusal to conduct the clinical trial.

(6) Within 30 days from the date of submission of the amended application under para 5, BDA shall inform the applicant in writing that:

1. they approve the conduct of the clinical trial, or
2. the trial cannot be carried out, stating the reasons for refusal.

(7) A copy of the clinical trial authorization shall be sent to the medical establishment pointed out in the application under Art. 50, para 1.

(8) In case BDA has not pronounced in the term fixed as per para 1, the applicant can start the investigation immediately.

Art. 52. (1) The Executive director of BDA shall pass a well-grounded refusal to conduct a clinical trial on the territory of the Republic of Bulgaria in those cases where:

1. there has not been provided enough evidence for the anticipated scientific and medical benefits from the use of the medical device in question;
2. there has not been provided enough for the safety of the trial subjects and/or the investigation team;
3. the provided information regarding clinical trial safety assessment is insufficient;

4. the operation of the device does not comply with its intended use defined by the manufacturer.

(2) Refusals under para 1 shall be subject to appeal under the terms of the Administrative Procedure Code.

(3) (amend. – SG 110/08, in force from 21.03.2010) The Bulgarian Drug Agency shall notify the regulatory authorities of the other member States, the regulatory authorities of the states of the European Economic Area and the European Commission of the refusal under para 1 and presents its reasons therefore.

Art. 53. (1) Applicant can make amendments in the investigation plan, other than essential ones, at any time.

(2) In cases referred to in para 1 the applicant shall keep the documentation relating to the amendments and shall provide it to the BDA and the ethics committee upon request.

Art. 54. (1) The assignor can implement planned essential amendments in the clinical trial plan.

(2) In the cases referred to in para 1, the applicant shall submit an application form along with the documents regarding the amendments, to the respective ethics committee and to BDA.

(3) The ethics committee passes a stand within 15 days from receiving the application under para 2 and presents it to the assignor and BDA.

(4) Within 15 days from the date of receiving the stand by the respective ethics committee, the Executive Director of BDA shall:

1. issue an amendment to the clinical trial authorization, approving the change in the trial plan,  
or

2. pass a well-grounded refusal for the substantial amendment referred to in para 1.

(5) The refusal under para 4, item 2 shall not be subject to appeal.

(6) If within the term under para 4 the applicant does not receive a refusal by BDA, he/she can carry out the clinical investigation according to the amended plan.

(7) (new – SG 110/08, in force from 21.03.2010) In the cases of par. 4, item 2 in case of multi-center testing the BDA shall notify the regulatory authorities of the affected member States or the regulatory authorities of the states of the European Economic Area of the refusal and presents its reasons therefore.

Art. 55. (1) Upon occurrence of any new event that is likely to affect the safety of the clinical trial subjects during its conduct, the sponsor and the investigator shall take appropriate urgent safety measures to protect the subjects against any immediate hazard.

(2) (amend. – SG 110/08) In the cases referred to in para 1, the assignor can:

1. make amendments in the clinical testing plan;

2. terminate the clinical testing prior to the scheduled in the clinical testing plan term.

(3) (amend. – SG 110/08) The assignor shall inform immediately the respective ethics committee and BDA:

1. of the undertaken measures, the reasons for them and the amendments made in the plan;

2. of the termination of the clinical testing prior to the scheduled in the clinical testing plan term.

(4) (new – SG 110/08) In the cases under Art. 3, item 1 the BDA shall notify the regulating bodies of the affected member States or the regulatory authorities of the states of the European Economic Area, participating in the testing, of the undertaken measures and of the amendments of the plan and shall present the justifications thereof.

(5) (new – SG 110/08) In the cases under Art. 3, item 2 the BDA shall notify the regulating bodies of the other member States, the regulatory authorities of the states of the European Economic



Area and the European Commission of the premature termination of the clinical testing and shall present the justifications thereof.

Art. 56. (1) (amend. – SG 110/08, in force from 21.03.2010) The assignor of the clinical testing is obliged to present to BDA upon request documentation containing:

1. general description of the device and of its purpose of use;
2. design drawings, production methods, including the ones related to sterilization, diagrams of components and details, ways of connection, etc.;
3. description and explanations of the drawings and diagrams and the operation of the medical device;
4. results from the risk analysis and a list of the applied fully or partially standards as per Art. 13, para 1 and a description of the adopted technical decisions for ensuring essential requirements conformity, where these standards have not been applied;
5. results of tests, carried out by a regulatory body of a Member State or by the European Medicines Agency for assessment of the quality and safety of the substance in the meaning of Art. 3, item 2, 3 or 4, as well as for assessment of its benefit in terms of device purpose of use;
6. the undertaken measures for reduction of the risk of infections, included in the risk management system in case of a device as per Art. 2, par. 1, item 3, for the manufacturing of which non-viable animal tissue or non-viable products, produced from animal tissues have been used;
7. the results of the engineering calculations and the accomplished inspections and technical tests.

(2) (amend. – SG 110/08, in force from 21.03.2010) The assignor of the clinical test is obliged to keep the documentation of par. 1 for a period of 15 years after the accomplishment of the clinical test – for the devices under Art. 2, para 1, item 2, and for implantable devices under Art. 2, para 1, item 3, and 5 years for the devices of Art. 2, par. 1, item 1.

(3) (amend. – SG 110/08, in force from 21.03.2010) The manufacturer is obliged to ensure a production process whereby the medical devices intended for clinical trials are produced in accordance with the documentation of par. 1.

Art. 57. (1) Within 90 days from completion of the clinical trial, the assignor presents to BDA and the respective ethics committee a final report containing a description of methodology and organization, critical assessment and statistical analysis of received data.

(2) The report under para 1 shall be signed by the assignor and by all investigators. If one of the investigators refuses to sign it, he/she shall enclose his/her reasons in writing.

(3) The report under para 1 shall summarize data received from all medical institutions and from all subjects in the trial.

(4) Personal data of the trial subjects which are included in the report under para 1 shall be coded.

Art. 58. (1) Bulgarian Drug Agency keeps a register of the issued and withdrawn clinical trial authorizations.

(2) Bulgarian Drug Agency shall organize and establish a system for registration, analysis and summary of all incidents related to medical devices that have occurred in the course of clinical trials.

(3) The medical devices pharmacovigilance procedure in the course of the clinical trial is provided in the as per under Art. 48, para 2.

Art. 59. (1) The Executive Director of BDA can temporary suspend the trial being carried out or terminate it by an order, provided that:

1. the trial is conducted under conditions other than the ones stated in the authorization;

2. there is information raising doubts about violating the scientific validity of the trial;
3. there is a risk for the safety of the subjects.

(2) Prior to undertaking any actions under para 1, BDA shall notify of their intentions:

1. the assignor and coordinating investigator, responsible for carrying out the trial at all sites,  
or,

2. the assignor and principal investigator, who is in charge of the relevant medical institution where the trial shall be terminated.

(3) Within 7 days after notification under para 2 the assignor and the principal and coordinating investigator can present written explanations to BDA.

(4) Para 2 shall not apply if there is imminent risk for the health and safety of the trial subjects.

(5) The order under para 1 can be subject to appeal under the terms of the Administrative Procedure Code, provided that the appeal does not suspend its enforcement.

(6) The principal or coordinating investigator notifies the clinical trial subjects of the order under para 1.

Art. 60. (amend. – SG 110/08) (1) In case of termination of clinical testing the Executive Director of BDA shall notify immediately the regulatory authorities of the Member States of the regulatory bodies of the states of the European Economic Area and the European Commission of the order referred to in Art. 59, par. 1 and shall present justifications thereof.

(2) In case of temporary suspension of the clinical testing the Executive Director of BDA shall notify immediately the regulatory authorities of the affected Member States or of the states of the European Economic Area, participating in the testing, of the ordinance referred to in Art. 59, par. 1 and shall present justifications thereof.

#### **Chapter four. NOTIFIED BODIES**

Art. 61. (1) Approval for conformity assessment of medical devices shall be granted to a natural or legal person registered under the Commercial Law by the Chairman of the State Agency for Metrology and Technical Surveillance.

(2) The person under para 1 submits a written application to the Chairman of the State Agency for Metrology and Technical Surveillance specifying the devices and procedures for which he/she applies.

(3) Enclosed to the application under para 2 shall be the following:

1. a certificate as per Art. 33 of the Law of the Commercial Register in case the person is registered under the Commercial law or a copy of the act of formation in case the person is established according to a law or an act of the Council of Ministers;

2. a certificate that the person has not declared insolvency or is not in insolvency proceedings;

3. documents certifying that the person does not have any liabilities to the state or the municipality within the meaning of the Tax-insurance Procedure Code, ascertained by an enforced act of competent authority, or liabilities to Insurance funds, unless deferred payment or postponement of the liabilities has been authorized by the competent body;

4. a copy of employment and/or civil agreements of the personnel, education documents, additionally acquired qualification;

5. a copy of agreement when the person participates in unions of trade union associations and organizations;

6. copies of agreements with subcontractors, when trials and investigations are assigned to other people;

7. a copy of insurance contract covering risks upon obligations performance in the course of conformity assessment activities;

8. a declaration that the person, personnel and subcontractors have not been involved in the design, manufacture, delivery and installation of the devices, which will be assessed, as well as that they are not authorized representatives or manufacturer's consultants;

9. a copy of conformity assessment procedures evidenced by documents, for which he/she applies;

10. a declaration of impartiality which guarantees that the fulfillment of employees' obligations is not influenced by moral pressure and financial incentives by people interested in the assessment results;

11. a statement that the personnel is bound by the requirement for professional secret protection regarding the information available in the course of his/her activity performance;

12. data concerning the professional experience of employees and subcontractors, if any, which demonstrate medical and technical competency and gained experience at assessment of devices pointed out in the application according to the applicable procedures, including experience in drawing up records, reports and certificates;

13. information about the technical devices needed for the conducting of trials and investigations which are part of the conformity assessment procedures and which are available at their own testing laboratories and/or contracted testing laboratories, and copies of accreditation assessments of the laboratories, if any;

14. a list of the standards as per Art. 13, para 1 or monographs of the official pharmacopoeia in the Republic of Bulgaria under Art. 13, para 2, or general technical specifications under Art. 13, para 3, referring to the devices enlisted in the application;

15. methods and instructions for device trial in case the standards under Art. 13, para 1 are not implemented, or monographs of the official pharmacopoeia in the Republic of Bulgaria as per Art. 13, para 2, or the general technical specifications of Art. 13, para 3;

16. copies of documents certifying their education, audit training, professional and audit experience according to the requirements of BDS EN ISO 19011 of the auditor who will carry out the assessment of the implemented quality system where the conformity assessment procedure requires that;

17. manual and procedures for the quality system;

18. document certifying paid fee for documentation assessment to the amount fixed in Art. 7, para 1.

(4) When the person applying for authorization for conformity assessment presents an accreditation certificate according to standards indicated in the regulation under Art.18, it is accepted that he/she has a functional quality system referring to the requirements for independence, equity, confidentiality and has the needed competence. In this case the person does not present the documents under para 3, item 8, 10, 11 and 17.

Art. 62. (1) The Chairman of the State Agency for Metrology and Technical Surveillance shall appoint by an order a commission of experts to assess the submitted documentation under Art. 61, para 3 or 4.

(2) The commission under para 1 consists of representatives of the State Agency for Metrology and Technical Surveillance, appointed by its chairman, and of BDA, designated by its Executive Director.

(3) Where necessary, to the commission under para 1 may be drawn in external experts who have gained experience and knowledge in the field of the respective devices.

(4) If there are non-conformities and shortcomings in the documentation under para 1, the chairman of the State Agency for Metrology and Technical Surveillance shall provide the applicant with a copy of the expert assessment of the commission under para 1 and sets a two-month term for their

removing. The term under Art. 63, para 5 shall stop running until the non-conformities and shortcomings are removed.

(5) If the applicant does not remove the non-conformities and shortcomings within the term under Art. 4, the procedure shall be terminated.

Art. 63. (1) Within a two-month term from the date of submission of the valid documentation under Art. 61, para 3 or 4, the commission as per Art. 62, para 1 shall carry out an on-site inspection in order to ascertain the competency of the applicant and his/her abilities to perform the declared conformity assessment procedures. For the purposes of performing an on-site inspection a fee to the amount fixed in the tariff as per Art. 7, para 1 shall be paid.

(2) In case during the on-site inspection are established non-conformities between submitted documents under Art. 61, para 3 or 4 and the conformity assessment requirements defined in ordinances as per Art. 18, the chairman of the State Agency for Metrology and Technical Surveillance shall notify the applicant in writing and shall fix a two-month term for their removing. The term under para 5 stops running till removing the non-conformities.

(3) If the applicant does not remove the non-conformities found within the two-month term fixed under para 2, the chairman of the State Agency for Metrology and Technical Surveillance shall refuse to issue an authorization by a well-grounded order.

(4) Within two months from the on-site inspection, the commission under para 1 passes a stand to the chairman of the State Agency for Metrology and Technical Surveillance along with a reasoned offer for approval of notification or refusal.

(5) Within six-month term from the submission of the documentation as per Art. 61, para 3 or 4 the chairman of the State Agency for Metrology and Technical Surveillance shall inform the applicant that he/she is approved for notification or shall issue a reasoned order for refusal.

Art. 64. (1) Within three days from the notification as per Art. 63, para 5, the chairman of the State Agency for Metrology and Technical Surveillance shall announce to the European Committee and the Member States the bodies as per Art. 61, para 1 that have been approved.

(2) The identification number of the bodies under para 1, called "notified bodies", is defined by the European Committee.

(3) The chairman of the State Agency for Metrology and Technical Surveillance shall issue an authorization to carry out conformity assessment to the notified bodies under para 2.

(4) The name and the address of the body referred to in para 2, the medical devices and conformity assessment procedures shall be published in the Official Journal of the European Union.

Art. 65. The conformity assessment procedures may be carried out by conformity assessment bodies announced before the European Commission by other Member States.

Art. 66. The authorization to conduct conformity assessment shall contain:

1. name of the body that has issued the authorization;
2. name/company name, headquarters, business address and representative office of the notified body;
3. medical devices and conformity assessment procedures;
4. date of authorization issue;
5. identification number of the notified body as per Art.64 , para 2 .

Art. 67. (1) In the register under Art. 19 from the Law on technical requirements for products the following shall be specified:

1. data under Art. 66;

2. date of authorization suspension and the reason for it.

(2) Data under para 1 is published in the official bulletin of the State Agency for Metrology and Technical Surveillance.

Art. 68. (1) The notified bodies are obliged to notify the chairman of the State Agency for Metrology and Technical Surveillance in case of:

1. changes in the legal and accreditation status, the structure, scope of activity and conformity assessment procedures;

2. changes in the quality system, management or staff that affect the performance of the conformity assessment procedures;

3. change of the subcontractors;

4. changes in the circumstances related to the insurance as per Art. 61, para 3, item 7.

(2) The bodies under para 1 shall submit to the chairman of the State Agency for Metrology and Technical Surveillance the documents concerning the changes and a fee to the amount specified in the tariff under Art.7, para 1.

(3) Within one month term from the submission of the documents as per para 2, the committee of experts under Art. 62, para 1 passes a stand to the chairman of the State Agency for Metrology and Technical Surveillance for approving the changes.

(4) In those cases where changes under para 1 require an on-site inspection, the committee under Art. 62, para 1 shall pass a statement to the chairman of the State Agency for Metrology and Technical Surveillance for approving the changes within a two-month period.

(5) On the grounds of the statement under para 3 and para 4, the chairman of the State Agency for Metrology and Technical Surveillance issues an amendment to the authorization as per Art. 64, para 3 by an order.

(6) In case during the inspection of the documentation of para 2 or upon on-site inspection non-conformities and shortcomings regarding the requirements of the ordinances as per Art.18 are found, the committee under Art. 62, para 1 shall issue instructions and a deadline for their removing. The terms under para 3 and 4 cease running until the instructions are implemented.

(7) If the notified bodies do not implement the instructions under para 6, the chairman of the State Agency for Metrology and Technical Surveillance shall refuse to issue an amendment to the authorization by an order.

Art. 69. For the purpose of widening the scope of authorization to conduct conformity assessment an application form shall be submitted according to Art. 61.

Art. 70. (1) The notified bodies are obliged to present to the State Agency for Metrology and Technical Surveillance an annual report on their activity including information about conducted conformity assessments of medical devices, claims, complaints and measures undertaken by 31 January of the following year.

(2) A copy of the report under para 1 shall be presented to the Executive Director of BDA.

Art. 71. (1) Upon annual planned inspections, commissions assigned by an order of the chairman of the State Agency for Metrology and Technical Surveillance shall supervise the carrying out of conformity assessment procedures.

(2) Exceptional on-site inspections by the notified bodies may be carried out upon receiving signals, claims and complaints related to their activity.

(3) When during inspections are found omissions in the work of the notified bodies, the chairman of the State Agency for Metrology and Technical Surveillance shall issue instructions containing a deadline for removing them.

(4) The chairman of the State Agency for Metrology and Technical Surveillance issues an order for temporary ban on the activity of the notified bodies until removing the omissions under para 3. A copy of the order shall be forwarded to BDA.

Art. 72. (1) The chairman of the State Agency for Metrology and Technical Surveillance shall withdraw the authorization to conduct conformity assessment by an order if during the inspections it has been found that the notified body:

1. no longer complies with some of the conditions under which the authorization has been issued;
2. is no longer able to proceed with the conformity assessment procedures;
3. does not carry out the conformity assessment procedures in compliance with the requirements of the relevant ordinances as per Art. 18;
4. has not undertaken measures for removing the omissions referred to in Art. 71, para 3 within the fixed term.

(2) A copy of the order under para 1 shall be sent to BDA.

Art. 73. The chairman of the State Agency for Metrology and Technical Surveillance shall notify the European Commission and the Member States for the withdrawn authorizations as per Art. 72 and for the changes made according to Art. 68, para 1, item 1.

Art. 74. (1) The person who has been refused issue of an authorization as per Art. 63, para 5, can submit a new application for authorization not earlier than 6 months from the date of handing the order for refusal.

(2) The notified body whose authorization under Art. 72, para 1 has been withdrawn can submit an application for new authorization not earlier than one year from the date of handling the order for authorization withdrawal.

Art. 75. The refusal to issue an authorization to conduct conformity assessment as well as the order for authorization withdrawal can be subject to appeal under the terms of the Administrative Procedure Code.

Art. 76. (1) The notified body issues a certificate verifying the essential requirements conformity applicable to the device, with validity of 5 years, or makes a reasoned refusal.

(2) (amend. – SG 110/08) In case the notified body ascertains that a manufacturer has not fulfilled or has stopped fulfilling the requirements defined in the ordinances as per Art. 18, or the conditions, under which the certificate has been granted have changed, and in consideration of the level of nonconformity it withdraws the certificate or suspends temporarily its validity, or restricts its scope, until the manufacturer undertakes appropriate corrective measures and provides the required conformity.

(3) (amend. – SG 110/08) The notified body shall inform the State Agency for Metrology and Technical Surveillance (SAMTS) and BDA in cases of temporary suspension of certificate validity, of withdrawal or imposition of restrictions or where it assumes that their interference is necessary.

(4) (amend. – SG 110/08) The Bulgarian Drug Agency shall inform the regulatory authorities of the other Member States, the regulatory authorities of the states of the European Economic Area and the European Commission of the cases under par. 3.

Art. 76a. (new – SG 110/08) (1) The Notified bodies shall be obliged to provide to the SAMTS and to the BDA:

1. a copy of all issued certificates, information on refused certificates, on certificates the validity of which has been suspended temporarily, on the withdrawn certificates, on the modified or

supplemented certificates – every three months;

2. additional information and relevant documentation, related to the activities for conformity assessment – upon request.

(2) The notified bodies shall be obliged to provide to the other notified bodies of the Member States information on refused certificates, on certificates the validity of which has been suspended temporarily, on the withdrawn certificates, and upon request - on the granted certificates.

## **Chapter five. WHOLESALE TRADE IN MEDICAL DEVICES**

Art. 77. Wholesale trade in medical devices on the territory of the Republic of Bulgaria may be carried out by natural or legal persons who are registered as traders under the national legislation of a Member State or a state from the European Economic Area and are authorized for such activity issued by a regulatory authority of the respective state.

Art. 78. (1) The persons referred to in Art. 77 who wish to be given authorizations or certificates for wholesale trade in medical devices shall submit to BDA an application form approved by the Executive Director of BDA, to which shall be attached the following documents:

1. a certificate under Art. 33 of the Law of the Commercial Register, or any relevant document according to the national legislation of the relevant Member State or state from the European Economic Area.

2.(amend. – SG 110/08) a list of the categories of medical devices according to the nomenclature system BDS EN ISO 15225 for categorization of medical devices and of their respective manufacturers on paper and electronic medium;

3. a document for paid fee to the amount fixed in the tariff as per Art. 7, para 1.

(2) If they have available premises for storage and wholesale trade in medical devices on the territory of the Republic of Bulgaria, the persons under para 1 shall specify their address in the application form. In this case the following documents shall also be enclosed to the documentation under para 1:

1. (amend. – SG 110/08) usage permit or another substituting document, issued according to the Law for the Spatial Planning;

2. a document certifying the legal grounds for using these premises;

3. a declaration drawn up by the persons under para 1, stating:

a) that the premises meet the requirements for storage and wholesale trade in medical devices, specified in the list under para 1, item 2, according to their particular features and the manufacturer's instructions set out in the instructions for use, and,

b) that they own or have available means of transport ensuring their proper storage during distribution or transportation;

4. name, permanent address and correspondence address of the person in charge of the premises for storage and wholesale trade in medical devices, as well as a copy of the contract on the ground of which the said person has legal relationship with the applicant.

(3) The persons under Art. 77 who have a registration certificate or an authorization for wholesale trade in medical devices issued by a regulatory authority of another Member State or a state from the European Economic Area, shall submit to BDA:

1. a copy of the authorization or certificate for wholesale trade, certified by a notary in the Member State, along with a legalized translation in Bulgarian language;

2. the documentation under para 1, item 2 and 3.

(4) In case the persons under para 3 have available premises for storage and wholesale trade in

medical devices on the territory of Bulgaria they shall provide BDA with the additional documentation under para 2.

(5) Where the persons referred to in para 3 do have available premises for storage and wholesale trade in medical devices on the territory of Bulgaria they shall also present to BDA name and correspondence address of their authorized representative in the country.

Art. 79. (1) The Bulgarian Drug Agency shall consider the presented documents pursuant to Art. 78.

(2) Upon established imperfections in the documentation under para 1, BDA shall notify the applicant in writing of their elimination. The time limit under para 3 shall stop running from the notification date until the valid documentation is provided.

(3) Within 30 days from the submission of valid documentation, the Executive Director of BDA shall issue:

1. a certificate of wholesale trade in medical devices to the persons referred to in Art. 78, para 3.
2. authorization for wholesale trade in medical devices to persons other than the ones specified in item 1.

Art. 80. (1) Wholesale traders in medical devices shall submit to BDA an application form for amendment and/or addition, in case of change of:

1. the address of the premises for storage and wholesale trade in medical devices in the cases referred to in Art. 78, para 2 and 4;
2. the person under Art. 78, para 2, item 4 and/or their address;
3. the legal statute, headquarters and/or business address of the trader;
4. (suppl. – SG 110/08) the list of types of medical devices being traded and their respective manufacturers;
5. the name and/or address of the authorized representative as per Art. 78, para 5.

(2) (suppl. – SG 110/08) To the application form under para 1 shall also be appended the documents related to the change and a document of a collected fee of the amount, determined by the tariff under Art. 7, par. 1.

(3) Amendment certificates or authorizations shall be issued by the Executive Director of BDA within 15 days from the submission of application form under para 1. In case of change in the address of the premises for storage and wholesale trade in medical devices, the term shall be prolonged by 15 days.

(4) The persons under para 1 are obliged, within 10 days after termination of their activities relating to wholesale trade in medical devices, to notify in writing the Executive Director of BDA.

(5) In the cases referred to in para 4, the Executive Director of BDA shall terminate the effect of the issued authorization or invalidate the issued certificate for wholesale trade by an order.

Art. 81. The Bulgarian Drug Agency keeps a register of the issued certificates or authorizations for wholesale trade in medical devices, containing:

1. number and date of the certificates or authorizations for wholesale trade in medical devices;
2. name, headquarters and registered address of the persons under Art. 77;
3. termination date of authorizations or certificates under item 1;
4. address of the premises for storage and wholesale trade in medical devices;
5. name and address of the persons referred to in Art. 78, para 2, item 4;
6. name and address of the persons referred to in Art. 78, para 5.

Art. 82. (1) Wholesale traders in medical devices are obliged to trade only in medical devices the shelf life of which has not expired and which have:



1. affixed CE marking according to the requirements of Art. 15;
  2. (amend. – SG 110/08) affixed identification number of the notified body as per Art. 64, para 2, where the procedures, determined in the provisions of Art. 18 require its displaying;
  3. affixed name and registered address of the manufacturer and/or their authorized representative and the importer;
  4. instructions for use, except for devices that the present Law does not cover.
- (2) The persons under para 1 are obliged to maintain the premises referred to in Art. 78, para 2 in conformity with the requirements for storage of the respective type of device, determined by the manufacturer.
- (3) The persons under para 1 shall keep reports on:
1. the purchased and sold quantity in terms of types of devices, the purchase and sale date, the name and address of the wholesale traders or the sites as per Art. 83, para 1, items 2 through 4, that they have traded with;
  2. the warehouse stock of medical devices, batch number and shelf life.
- (4) The persons under para 1 provide and maintain a documented system for tracing the safety of medical devices placed on the market and for blocking and withdrawing from the market of medical devices which have revealed non-conformity with the safety requirements within the meaning of Chapter VII.
- (5) Together with the documentation under para 3, shall be stored the batch certificates of medical devices for a period of 5 years and shall be presented upon request to the persons referred to in Art. 86.

Art. 83. (1) Wholesale traders may carry out business transactions with medical devices, adhering to storage and distribution restrictions, with:

1. other wholesale traders within the meaning of this Law;
2. medical establishments;
3. health institutions;
4. pharmacies and drugstores;
5. (new – SG 110/08) The Ministry of Health, the Ministry of Defense, the Ministry of Interior for their own purposes, except for their departmental medical establishments, and also the State Agency "State reserve and war-time stock".

(2) (suppl. – SG 41/09, in force from 02.06.2009) The Minister of Health or a deputy minister authorized by him/her shall determine by an order the medical devices which can be sold at sites other than the ones specified in para 1.

Art. 84. (1) The persons referred to in Art. 86, para 2 shall carry out planned and unexpected inspections at the premises for storage and wholesale trade in medical devices.

(2) Persons referred to in para 1 may require, inspect and make copies of the documents under Art. 82, paras 3 and 4 and take samples and specimens of the devices under the terms of Art. 93, para 3.

(3) In case during the inspection it is established that medical devices do not comply with the requirements set out in Art. 82, para 1, items 1, 2 and 3, or that their shelf life has expired, the Executive Director of BDA shall temporarily suspend or revoke the authorization, or invalidate the wholesale trade certificate and shall order the devices placed on the market and/or put into service to be blocked and withdrawn.

(4) In case it is established that the premises for storage and wholesale trade do not meet the requirements determined by the manufacturer regarding certain device, the persons under para 1 shall give instructions and fix a term for eliminating these non-conformities.

(5) In case the inspection ascertains that there are shortcomings or imperfections in the documentation as per Art. 82, para 3 or in the system of Art. 82, para 4, the persons referred to in para 1

shall give instructions and fix a term for eliminating them.

(6) In case the non-conformities, shortcomings and imperfections are not eliminated within the terms under para 4 and 5, the persons referred to in para 1 shall present a statement to the Executive Director of BDA, including a proposal to withdraw the authorization or to invalidate the wholesale trade certificate.

(7) The orders of the Executive Director of BDA under para 3 and 6 may be appealed under the terms of the Administrative Procedure Code, and the appeal shall not suspend their implementation.

Art. 85. The Bulgarian Drug Agency shall notify the of Member States' regulatory authorities of authorizations or certificates for wholesale trade in medical devices which have been issued, temporary terminated and withdrawn, and the reasons for that.

## **Chapter six. MARKET SUPERVISION**

Art. 86. (1) Market supervision is exercised to ensure that the medical devices placed on the market and/or put into service meet the requirements of the Law and the ordinances as per Art. 18.

(2) Market supervision on the territory of the Republic of Bulgaria is carried out by BDA through inspectors and experts appointed by an order of the Executive Director.

Art. 87. (1) Market control is carried out by means of:

1. inspections of devices placed on the market and/or put into service;
2. taking samples and specimens of the devices and testing.

(2) Trials of medical devices may not be carried out by the notified bodies involved in the conformity assessment of the same devices.

Art. 88. Inspections of medical devices placed on the market and/or put into service shall be carried out according to:

1. approved in advance annual market supervision plan by groups of medical devices, respectively by the Executive Director of BDA, and
2. signals from other authorities and identified written signals from citizens.

Art. 89. Persons referred to in Art. 86, para 2 shall conduct inspections at sites as per Art. 83, para 1, items 2 through 4 and para 2, as well as at the production premises of medical devices.

Art. 90. (1) (prev. Art. 20 – SG 110/08) Persons referred to in Art. 86, para 2 shall carry out inspections for:

1. availability of "CE" marking and for its compliance with the requirements of the law;
2. (amend. – SG 110/08) identification number of the notified body as per Art. 64, para 2, where the procedures, determined in the provisions of Art. 18, require its displaying;
3. availability of instructions for use and conformity of its content with the requirements of ordinances as per Art.18, exclusive of the devices referred to in Art. 2, para 1, item 3 which fall in class I and class IIa, if they can be safely used without instructions for use;
4. (amend. – SG 110/08) presence of a label and conformity of its content with the requirements contained in the provisions of Art. 18;
5. presence of name and headquarters of manufacturer, or their authorized representative, or the importer on the medical device;
6. shelf life of the medical device;

7. (revoked – SG 110/08).

(2) (new – SG 110/08) The persons of Art. 86, par. 2 shall inspect the fulfillment of the requirement of Art. 27, par. 1 and Art. 28, par. 1 and 6.

Art. 91. (1) Where during inspection the persons as per Art. 86, para 2 establish that the medical devices are placed on the market and/or put into service without "CE" marking or with expired shelf life, they shall pass a stand to the Executive Director of BDA with a proposal for issuing an order to block and withdraw the device from the market.

(2) (amend. – SG 110/08) If upon inspection the persons referred to in Art. 86, para 2 establish that medical devices are placed on the market and/or put into service without instructions for use and/or without a label or the content of the label does not comply with the requirements of the ordinances under Art. 18, and/or manufacturer's name and place of business or those of his/her authorized representative and of the importer are not displayed on the device, they shall give instructions to the manufacturer or his/her authorized representative with a deadline for removing the breach that has been ascertained.

(3) In case the breach under para 2 is not eliminated within the deadline the persons as per Art. 86, para 2 shall pass a statement to the Executive Director of BDA along with a proposal for issuing an order to block and withdraw the device from the market.

(4) (amend. – SG 110/08) Where the requirement of Art. 90, item 2 has not been met or the affixed marking does not comply with the requirements of Art. 15, or there is a doubt that the CE marking has been affixed unjustified, the persons referred to in Art. 86, para 2 shall require from the manufacturer or his/her legal representative or from the importer to present within 10 days after the date of notification:

1. conformity declaration;
2. technical documentation as per Art. 14, para 1.

Art. 92. (1) Persons as per Art. 86, para 2 pass a statement to the Executive Director of BDA who shall issue an order to block and ban on the distribution of devices, if within the term under Art. 91, para 4 the conformity declaration and technical documentation have not been submitted, except for the cases when the term under Art. 14, para 3 has expired.

(2) Within 30 days from the date of handling the order under para 1, the manufacturer, his/her authorized representative or the importer are obliged to withdraw the device from the market.

Art. 93. (1) (amend. – SG 110/08) When upon inspection of the technical documentation under Art. 14, para 1 and of the conformity declaration of Art. 91, par. 4, item 1 doubts arise that the device does not meet the essential requirements, set in the ordinances under Art. 18, the persons under Art. 86, para 2 shall take samples or specimens of the device to be tested.

(2) The investigation is carried out in a laboratory accredited by the Executive Agency "Bulgarian Accreditation Service" or in laboratory accredited by an authority of a Member State or a state from the European Economic Area.

(3) (amend. – SG 82/09, in force from 16.10.2009) The terms and the manner of taking samples and specimens of medical devices for testing are determined with an ordinance by the Minister of Health and by the Minister of Economy, Energy and Tourism.

(4) In case of the results of the conducted laboratory tests are disputed, within 7 days from the date of receiving the results from the initial test, the manufacturer or his/her authorized representative submits to BDA a written request for conducting a second test.

(5) The second test under para 4 shall be carried out by experts who have not participated in the initial test.

Art. 94. (1) In the cases referred to in Art. 93 the Executive Director of BDA shall issue an

order for temporary ban on the distribution or use of the device in question.

(2) Copy of the order under para 1 shall be given to the manufacturer or his/her authorized representative or the importer.

Art. 95. Where persons as per Art. 86, para 2 find that the nonconformity with the essential requirements can be eliminated, they pass a statement to the Executive Director of BDA and give instructions with a deadline, coordinated with the manufacturer or his/her authorized representative, for carrying out the required corrective actions or for complete conformity assessment of the device with the essential requirements.

Art. 96. (1) If the persons referred to in Art. 86, para 2 establish that the nonconformity with the essential requirements can not be eliminated; they shall pass a statement to the Executive Director of BDA.

(2) On the grounds of the statement under para 1, the Executive Director of BDA issues an order for block and ban on the distribution or use of the device and arranges its withdrawal from the market within 30 days from the date of handling the order to the manufacturer or his/her authorized representative or the importer.

(3) BDA notifies the regulatory authority of the Member State where the manufacturer or his/her authorized representative and the importer are established of the order under para 2.

Art. 97. The orders as per Art. 92, para 1, Art. 94, Art. 96, para 2 and Art. 99, para 1 are subject to appeal under the terms of the Administrative Procedure Code, provided that the appeal does not stop their enforcement.

Art. 98. (1) In case during the trial under Art. 93 it is established that the medical devices do not comply with the essential requirements, the expenses for taking samples or specimens for testing are on the account of the manufacturer, his/her authorized representative or the importer.

(2) In case during the test under Art. 93 it is ascertained that the medical devices comply with the essential requirements, the expenses for taking samples or specimens for testing are on the account of BDA.

Art. 99. (1) (amend. – SG 110/08; suppl. – SG 41/09, in force from 02.06.2009) Upon a justified proposal by the Executive Director of BDA, where this is in public health interest and/or is required for the implementation of the national health policy, the Minister of Health or a deputy minister authorized by the latter may temporary by an ordinance:

1. prohibit launching on the market and/or putting into operation, or
2. prohibit the distribution, or
3. limit the scope of operation or
4. impose additional requirements for placing on the market and/or putting into service of a device or group of devices.

(2) (suppl. – SG 110/08) In the cases referred to in para 1 BDA shall notify the European Commission and regulatory authorities of the Member States and regulatory authorities of the states of the European Economic Area of the order, the reasons for it and the measures that have been undertaken.

Art. 100. (1) Persons referred to in Art. 86, para 2 shall be insured at the expense of BDA budget against accidents which can occur during or on occasion of fulfillment of their official duties.

(2) Upon inspections persons under Art.86, para 2 can ask for cooperation the Regional Inspectorate of Public Health Protection and Control, the bodies of the Ministry of Inferior and the

competent authorities of local self-government.

Art. 101. BDA publishes on its web site information about the devices for which there is an order issued as per Art. 91, para 1, Art. 92, para 1, Art. 94 and Art. 96, para 2.

Art. 102. Persons referred to in Art. 86, para 2 are obliged:

1. not to disclose facts and circumstances that have become known to them during or in relation to their official duties.
2. to use the documents and information obtained only for the purposes of market control;
3. to present their identity papers during inspections.

## **Chapter seven. INCIDENTS NOTIFICATION AND EVALUATION SYSTEM**

Art. 103. (1) Manufacturers shall be obliged to create and maintain a documented system for tracing the safety of medical devices manufactured by them and placed on the market/put into service on the territory of Member States, of states from the European Economic Area and third countries, as well as to have at their disposal the mechanisms for implementation of the necessary corrective actions.

(2) The system under para 1 shall be applied to medical devices which:

1. have CE marking;
2. do not have CE marking in case the incident or the potential incident relating to them under Art. 106, para 1 and 2 requires performance of corrective actions applicable to devices as per item 1.

(3) The system shall not apply to devices intended for clinical trials and devices for operation assessment.

(4) The system under para 1 includes examination of safety of devices under para 2 that have been placed on the market and/or put into service by way of:

1. collecting, documenting and analyzing reports for events under Art. 105 by medical experts, patients, persons installing, maintaining and calibrating the devices, and BDA;
2. analysis of results from additional tests on the devices carried out by the manufacturer;
3. collecting, recording and analyzing data from scientific literature.

Art. 104. (1) (prev. Art. 104 – amend. SG 110/08) Doctors, dentists other medical experts, as well as persons installing, maintaining and calibrating the devices are obliged to inform immediately the BDA about events as per Art. 105 at the sites under Art. 83, para 1, items 2 and 3.

(2) (new – SG 110/08) The Bulgarian Drug Agency shall provide to the manufacturer or to his/her authorized representative the information under par. 1 within three days after its receipt.

Art. 105. (1) The manufacturer shall inform BDA of any trouble or deterioration in the characteristics of the device manufactured by him/her, and/or in its operation, as well as of incomplete or inaccurate information on its label or instructions for use, which has caused death or serious health damage, or which is likely to cause death or serious health damage to a patient, medical expert or third persons on the territory of the Republic of Bulgaria.

(2) Manufacturers shall also inform BDA of any technical or medical cause related to the device's characteristics or operation, which leads to regular withdrawal from the market of the same type of devices due to the reasons specified in para 1.

Art. 106. (1) The manufacturer shall provide BDA with an advance report within 10 days of receipt of information about an event as per Art. 105 which has caused death or serious health damage,

and hereafter referred to as incident.

(2) The manufacturer shall submit to BDA an advance report within 30 days of receipt of information about an event under Art. 105 which could have caused death or serious health damage that were averted due to favourable circumstances or medical intervention, and hereafter referred to as potential incident.

(3) In case the incident or potential incident concerns devices of class IIa, Iib or III, or in vitro diagnostic medical devices from List A and List B, or self-testing devices, and has occurred in a third state, the manufacturer shall submit to BDA, within the term under para 1 or 2, an advance report in those cases where a notified body as per Art. 64, para 2 has carried out conformity assessment of the device related to the incident.

(4) In case the incident or potential incident concerns devices of class I or in vitro diagnostic medical devices that are not from List A and List B and are not for self-testing, and has occurred in a third state, the manufacturer shall submit to BDA, within the term under para 1 or 2, an advance report in those cases where the manufacturer or their authorized representative is registered at BDA according to Chapter II.

Art. 107. When the incident or potential incident is a result of combined use of two or more individual devices and/or accessories produced by different manufacturers, each manufacturer shall provide BDA with an individual report under Art. 106.

Art. 108. Immediately upon receiving information for an incident or potential incident, manufacturers shall notify their authorized representative as per Art. 10, para 2, the wholesale trader, and the notified body that carried out the assessment of the device's conformity with essential requirements.

Art. 109. (1) The Bulgarian Drug Agency maintains a system for registration, analysis and summarizing of incidents or potential incidents related to medical devices.

(2) The Bulgarian Drug Agency publishes on its web page the manuals for tracing the safety of medical devices, issued by the European Commission and the European Medicines Agency.

Art. 110. (1) The Bulgarian Drug Agency registers in the system under Art. 109, para 1 the data from the advance report of the manufacturer and assesses the provided information.

(2) The Bulgarian Drug Agency carries out supervision on the manufacturer's procedures regarding the investigation of the incident or potential incident and may issue directions and instructions.

(3) During the investigation of the incident or potential incident BDA assists the manufacturer, where necessary, to contact:

1. the notified body that has performed conformity assessment;
2. regulatory authorities of other affected Member States or states from the European Economic Area;
3. regulatory authorities of Member States or states from the European Economic Area for medical devices in the case of incidents or potential incidents with devices as per Art. 3, item 2, 3 and 4;
4. other manufacturers in the cases referred to in Art. 107;
5. users of the device or third persons.

Art. 111. In case the advance report as per Art. 106 indicates corrective actions, or contains the conclusion that the incident threatens the safety of patients, medical experts or third persons however corrective actions have not been defined yet, BDA sends a report to the regulatory authorities of Member States, states from the European Economic Area, and the European Commission.

Art. 112. (1) Within three months from the submission of the report as per Art. 106, the manufacturer draws in and presents to BDA a final report in a form approved by the Executive Director.

(2) The report under para 1 may contain one of the following conclusions:

1. it is not necessary to take any measures;
2. additional tracing of the device or batch of devices that have been put into service at the sites as per Art. 83, para 1, item 2 and 3;
3. distribution of information to medical experts at sites under item 2 and at pharmacies and drugstores in the form of written recommendation prepared by the manufacturer;
4. corrective actions in the course of future production;
5. corrective actions on the device put into service at sites as per item 2;
6. withdrawal of the device or batch of devices that have been placed on the market and/or put into service.

Art. 113. (1) In the cases referred to in Art. 112, para 2, item 2, BDA shall exercise control over the manufacturer's activity on the territory of the Republic of Bulgaria.

(2) In the cases of Art. 112, para 2, item 3, BDA shall assess the contents of the written recommendation and discuss with the manufacturer the addressees of the recommendation and its way of distribution.

(3) In the cases referred to in Art. 112, para 2, item 5, BDA can carry out an inspection on the spot.

(4) The Executive Director of BDA shall issue an order that the manufacturer blocks or withdraws the device or batch of devices with which the incident or potential incident has happened, in case it is ascertained that the manufacturer has not:

1. carried out corrective actions within the term specified by him/her in the report under Art. 112;
2. withdrawn the device or batch of devices from the market within the term specified by him/her in the report as per Art. 112;

(5) The terms and procedures for blocking, withdrawal and/or destruction of devices which do not meet the requirements of this Act shall be determined by an ordinance of the Minister of Health.

Art. 114. (1) The Bulgarian Drug Agency shall publish on its web site a list of the devices included in the ordinance under Art. 113, para 4.

(2) In those cases where the devices under para 1 are being sold at sites as per Art. 83, para 2, BDA informs the public through BTA and the mass media.

(3) The Executive Director of BDA issues a report on the incident that has occurred or the potential incident in cases referred to in Art. 112 and forwards a copy to the European Commission and the regulatory authorities of the Member States.

Art. 115 (1) Any direct notice to BDA regarding an incident or potential incident with medical device on the territory of the Republic of Bulgaria, handed by an identified person in writing, shall be documented in the system under Art.109.

(2) Within three days after receiving the notice for the incident or potential incident under para 1 BDA informs the manufacturer so that he/she undertakes the necessary measures defined under Art.106 - 108 and Art.112.

Art. 116. BDA can be coordinating regulatory authority:

1. in the case of incident or potential incident which has occurred on the territory of more than one Member State or a state from the European Economic Area, and

2. in the event that the incident or the potential incident is registered for the first time on the territory of the Republic of Bulgaria, or

3. where the body which has carried out the conformity assessment of the device with the essential requirements has obtained an authorization under Chapter IV, if the incident or the potential incident has occurred with devices from class IIa, IIb or class III, or in-vitro diagnostic medical devices from list A or list B, or self-testing devices, or

4. in case the manufacturer or their authorized representative is registered at BDA under the terms of Chapter II, if the incident or the potential incident has occurred with devices from class I or in-vitro diagnostic medical devices which are not included in list A and list B and are not for self-testing ones.

Art. 117. Personal data of the source of notice shall be stored by BDA according to the requirements of Law for Protection of the Personal Data.

### **Chapter eight. EUROPEAN DATABASE**

Art. 118. Immediately upon receipt, the Executive Director of BDA presents to the European database the following information in a standard format:

1. (amend. – SG 110/08) data regarding the registration of the manufacturers or the authorized representatives of Art. 29 and the devices under Chapter II, except for the devices, which are customized;

2. data obtained from clinical studies of medical devices under the terms of Chapter III;

3. data obtained upon tracing the safety of medical devices placed on the market and/or put into service on the territory of the Republic of Bulgaria under Chapter VII;

4. data regarding the issue, change, supplement, temporary termination, withdrawal or refusal of certificates by the notified bodies according to the procedures specified in the ordinances under Art. 18.

### **Chapter eight. "A" CONFIDENTIALITY (NEW – SG 110/08, IN FORCE FROM 21.03.2010)**

Art. 118a. (new – SG 110/08, in force from 21.03.2010) (1) The officials and the persons, applying this law and the secondary legislative documents related to its application, shall be obliged not to disclose any information, obtained for and with regard to fulfillment of their obligations.

(2) The provision of par. 1 shall not apply with regard to:

1. exchange of information between officials, between notified bodies and between officials and notified bodies;

2. disclosure of information which has as an objective to provide humans safety and health;

3. provision of information in case of prosecution proceedings.

(3) Shall not be confidential the information:

1. about the registration of the persons, launching medical devices on the market pursuant to the provisions of Chapter two;

2. which is provided to the users by the manufacturer, by his/her authorized representative or by the wholesaler concerning the measures undertaken according to the provisions of Chapter seven;

3. is contained in the granted, modified, supplemented and withdrawn certificates and in the certificates, the validity of which is temporarily suspended.



**Chapter nine.**  
**ADMINISTRATIVE PUNITIVE PROVISIONS**

Art. 119. Whoever places on the market and/or puts into service medical devices, the conformity of which has not been assessed in accordance with this Law and the acts for its implementation, shall be imposed with a fine from 10 000 to 20 000 BGN.

Art. 120. Whoever draws up or uses declaration of conformity with contents that does not meet the requirements set out in Art. 18, shall be imposed with a fine from 3000 to 8000 BGN, unless the act is a crime.

Art. 121. Whoever places on the market and/or puts into service medical devices, whose CE marking violates the requirements under para 15, shall be imposed with a fine from 5000 to 1000 BGN.

Art. 122. Whoever places on the market and/or puts into service medical devices with CE marking without having assessed their conformity with the essential requirements, set out by the ordinances as per Art. 18, shall be imposed with a fine from 10 000 to 20 000 BGN.

Art. 123. Persons who present medical devices at exhibitions, trade fairs, demonstrations, promotions, scientific and technical conferences in violation of Art. 15, para 11 shall be punished by a fine amounting from 500 to 1000 BGN.

Art. 124. Whoever places on the market and/or puts into service medical devices in violation of the provision of Art. 16, shall be punished by a fine amounting from 5000 to 10 000 BGN.

Art. 125. Whoever places on the market and/or puts into service medical devices without instructions for use, except for the devices referred to in Art. 2, 1, item 3 falling in class II and class Iia, in case such may be utilized safely without instructions for use, shall be punished by a fine amounting from 3000 to 5000 BGN.

Art. 126. Whoever places on the market and/or puts into service systems and/or sets of medical devices intended by the manufacturer for sterilization before use in violation of the requirements of this Law and the acts related to its implementation, shall be punished by a fine amounting from 10 000 to 15 000 BGN.

Art. 127. Whoever places on the market and/or puts into service custom-made medical devices in violation of the requirements of this law, shall be punished by a fine amounting from 5000 to 10 000 BGN.

Art. 128. Whoever carries out trade in medical devices without CE marking affixed, shall be punished by a fine amounting to 10 000 BGN.

Art. 129. (1) A manager of a medical establishment who allows use of medical devices without affixed CE marking , except for the custom-made devices, and the ones which have been put into service before the entry into force of this Law, as well as the devices referred to in Art. 12, para 1, shall be punished by a fine amounting from 2000 to 10 000 BGN.

(2) The same punishment shall be imposed on a manager of a medical or health institution who allows utilization of devices without instructions for use or devices whose shelf life has expired.

Art. 130. Whoever carries out wholesale trade in medical devices whose shelf life has expired, shall be punished by a fine amounting to 10 000 BGN.

Art. 131. A wholesale trader of medical devices, who breaches the requirements referred to in Art. 82, para 2, shall be punished by a propriety sanction amounting to 5000 BGN.

Art. 132. A wholesale trader of medical devices, who breaches the requirements referred to in Art. 82, para 3, 4 or 5 shall be punished by a propriety sanction amounting to 1000 BGN.

Art. 133. A wholesale trader of medical devices, who breaches the requirements referred to in Art. 82, para 1, items 2, 3 or 4 shall be punished by a propriety sanction amounting to 5000 BGN.

Art. 134. Whoever carries out wholesale trade in medical devices without issued authorization certificate for wholesale trade in medical devices, shall be punished by a fine amounting to 10 000 BGN.

Art. 135. A wholesale trader who breaches the regulation of Art. 80, para 1 shall be punished by a propriety sanction amounting to 3000 BGN.

Art. 136. A wholesale trader who breaches the regulation of Art. 80, para 4 shall be punished by a propriety sanction amounting to 1000 BGN.

Art. 137. Whoever carries out retail trade in medical devices without CE marking affixed, or in medical devices whose shelf life has expired, shall be punished by a fine amounting to 10 000 BGN.

Art. 138. Whoever carries out retail trade in medical devices outside the sites as per Art. 83, para 1, item 4 and para 2, shall be punished by a fine amounting to 10 000 BGN.

Art. 139. (amend. – SG 110/08) Whoever places on the market and/or puts into service medical devices on the territory of the Republic of Bulgaria without being registered within the prescribed term, shall be punished by a fine amounting to 5000 BGN.

Art. 140. (amend. – SG 110/08, in force from 21.03.2010) Whoever violates the requirements of Art. 27, para 3, Art. 28, para 7, Art. 29, para 2 and Art. 30 shall be punished by a fine amounting to 3000 BGN.

Art. 141. (1) Whoever breaches the requirements for carrying out clinical trials, if this does not constitute a crime, shall be punished by a fine amounting from 5000 to 10 000 BGN, and in the event of repeated violation - a fine amounting from 10 000 to 20 000 BGN.

(2) A medical expert who has committed violations under para 1 may be punished with deprivation of right to exercise the profession for a period from six months to two years.

(3) The punishment under para 2 shall be imposed by the Minister of Health upon proposal by the executive director of BDA.

Art. 142. A notified body, which fails to meet the requirement as per Art. 68, para 1, shall be punished by a sanction amounting from 2000 to 5000 BGN.

Art. 143. A notified body, which fails to meet the requirement as per Art. 70, para 1, shall be punished by a propriety sanction amounting to a maximum of 5000 BGN.

Art. 143a. (new – SG 110/08) A notified body, which fails to meet the requirement as per Art. 77a, para 1, shall be punished by a propriety sanction amounting to a maximum of 5000 BGN.

Art. 144. Whoever impedes the persons as per Art. 86, para 2 to fulfill their official duties according to the provisions of Chapter VI, shall be punished by a fine amounting from 6000 to 10 000 BGN.

Art. 145. A manufacturer of medical devices who violates the provision of Art. 103, para 1 shall be punished by a propriety sanction amounting from 5000 to 10 000 BGN.

Art. 146. A manufacturer of medical devices who violates the provision of Art. 107, shall be punished by a propriety sanction amounting from 10 000 to 20 000 BGN

Art. 147. Whoever does not inform about an incident or a potential incident related to a medical device according to Art. 104, shall be punished by a fine amounting from 1000 to 2000 BGN.

Art. 148. Whoever does not follow an order of the Executive director of BDA under Art. 113, para 4 shall be punished by a fine amounting from 10 000 to 20 000 BGN.

Art. 149. Whoever breaches the provisions of this Law or the acts related to its implementation, apart from the cases referred to in Art. 119 through Art. 148, shall be punished by a fine amounting from 3000 to 5000 BGN.

Art. 150. Whoever does not follow an order or instruction of BDA shall be punished by a fine amounting from 1000 to 3000 BGN.

Art. 151. (1) Where the breaches referred to in Art. 119 through 150 are committed by legal entities or sole traders, property sanctions shall be imposed. The amount of the propriety sanctions imposed may not be less than the double size of the minimum amount of the respective fines and may not exceed the double amount of the minimum amount of the respective fines fixed.

(2) Imposing propriety sanctions on the officials who have been found guilty does not exclude imposing fines on them.

Art. 152. (1) (suppl. – SG 110/08) Breaches of this Law shall be established by acts compiled by inspectors and experts, appointed by an order of the Executive director of BDA, except for the cases of par. 3.

(2) (suppl. – SG 110/08) Penal decrees shall be issued by the Executive director of BDA, except for the cases of par. 3.

(3) (new – SG 110/08) The violations under Art. 68, par. 1, Art. 70, par. 1 and Art. 76a, par. 1 shall be established by acts compiled by experts, appointed by an order of the Chairman of the SAMTS and the penal decrees shall be issued by the Chairman of the SAMTS or by empowered by him/her officials.

Art. 153. The drawing up of the acts, the issue, the appeal and the execution of the penal decrees shall be carried out pursuant to the Law for the Administrative Breaches and Penalties.

### **Additional provisions**

§ 1. Within the meaning of this Law:

1. "Active implantable medical device" means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain in the body after the procedure.

2. "Active medical device" means any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity.

3. "Valid documentation" means documentation which meets the requirements in terms of contents and completeness provided for in the respective procedure under this Law.

4. "Importer" means natural or legal person established on the territory of a Member State or a state from the European Economic Area, who imports medical devices on the European Union market from third countries.

5. "Assignor of clinical investigation" is the manufacturer or their authorized representative in charge of initiation, management and/or financing of a clinical trial.

6. "Principal investigator" is the leader of the investigation team, carrying out clinical trial.

7. "Good clinical practice" means the entirety of internationally acknowledged ethical and scientific quality requirements which are to be met when planning, conducting, accounting and reporting of clinical trials.

8. "Member State" means a Member State of the European.

9. "Data allowing identification of the device" includes:

a) information about the manufacturer, model and type number of the device, including software and appliances;

b) intended use determined by the manufacturer, including clinical indications and contraindications during use and identification of the groups of patients for whom it has been designated;

c) description of the device – description of materials that come into contact with human tissues or liquids, whether the device comprises a medicinal product, human and/or animal tissues or derivatives, or biologically active substances;

d) instructions for installation and use of the device, in case there are any special terms of preservation or function requirements – preliminary preparation before use – sterilization in cases of repeated use, safety check, measures that should be undertaken before use;

e) recommended training and experience required for use of the device;

f) description of the required medical and surgical procedures related to the use of the device;

10. "Device for self-testing" means any in-vitro diagnostic medical device intended by the manufacturer to be able to be used by lay persons in a home environment.

11. "Invasive medical device for continuous use" means any active medical device which is intended to be totally or partially introduced to the human body through a natural orifice or its surface, and which is intended to remain for more than 30 days.

12. "In-vitro diagnostic medical device" means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

a) concerning a physiological or pathological state, or

b) concerning a congenital abnormality, or

c) to determine the safety and compatibility with potential recipients, or

d) to monitor therapeutic measures.

In vitro diagnostic medical devices are also considered to be the devices for self-testing, specimen receptacles, except for the products for general laboratory use unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic

examinations.

13. "In vitro diagnostic device for performance evaluation" means any in vitro diagnostic device intended by the manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analyses or in other appropriate environments outside production premises;

14. "Informed consent" means a decision, which must be written, dated and signed, to take part in a clinical trial, taken freely after being duly informed of its nature, significance, implications and risks and appropriately documented, by any person capable of giving consent or, where the person is not capable of giving consent, by his or her legal representative; if the person concerned is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases.

15. "Calibrator and control material" refer to any substance, material or Art. intended by their manufacturer either to establish measurement relationships or to verify the performance characteristics of a device in conjunction with the intended use of that device.

15a. (new – SG 110/08, in force from 21.03.2010) "Clinical data" is the information, gathered in the course of device usage concerning its safety and/or its functioning. Clinical data shall be obtained from:

a) the results, obtained in the course of carrying out of clinical testing or the tested medical device, or

b) data of clinical test/tests or data from other studies, published in the research papers, on similar medical device, the equivalency or which with the tested device can be proven, or

c) published and/or non-published reports of another clinical examination of the tested device or of a similar medical device, the equivalency of which with the tested device can be proven.

16. "Coordinating investigator" is the person who coordinates the investigators during multi-centre clinical trials.

17. "Corrective actions" may include withdrawal of the device which has been put into service; issue of recommendations in writing specifying the measures that shall be undertaken; further tracing or modification of the device that has been put into service with the purpose of characteristics and performance improvement; amendment of the project; change of individual components of the device or change in the production process in the event of future manufacturing of such Art.s; amendment of the contents of the label or the instruction for use, etc.

14. "Critical analysis" means:

a) short description of the medical device – intended operation, type, characteristics;

b) analysis of the relevant literature and all the information available;

c) critical analysis of the damages identified while using the device, the related risks and suitable safety measures as regards to patients, medical personnel and third parties;

d) selection methods regarding the literature sources used, the statistics analysis methods, assessment methods applied, the investigation type and duration, heterogeneity and the population included in the investigation;

e) final assessment of the benefit from the use of the device compared to the risk, taking into account the modern scientific achievements and the medical practice;

f) conclusion pointing out whether the purposes set out in the tasks have been fulfilled, identification of shortcomings in the conformity assessment of the device with the essential requirements regarding safety and intended clinical effect, and, where necessary, reasons for conducting clinical trials – goals and plan of the investigation.

19. "A person, established on the territory of a Member State or a state from the European Economic Area" means a person registered according to the civil or trade legislation of a Member State or a state from the European Economic Area, or an entity established by a legislation act, having a business and registered office in a Member State or a state from the European Economic Area.

20. "Personal protective equipment" shall mean any equipment or device designed to protect a person against one or more hazards likely to endanger his safety and health. Personal protective

equipment shall also be considered the following:

a) entirety of equipment or devices or means interrelated by the manufacturer for the purpose of protecting a person from one or numerous hazards which may occur at the same time;

b) protective equipment or device connected with a personal device with no protective function in a manner allowing or not separation, utilized by a person for a certain activity.

c) replaceable compounds of a personal protective device, which are essential for its proper functioning and which are being used solely for the same personal device.

21. (amend. – SG 110/08, in force from 21.03.2010) "Medical device" means any instrument, apparatus, appliance, software, material or other device, whether used alone or in combination, including software, designated by the manufacturer to be used specifically for diagnostic and/or therapeutic purposes and required for its proper functioning, which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means, but which may be assisted in its function by such means and which is intended by the manufacturer to be used for human beings for the purpose of:

a) diagnosis, prevention, monitoring, treatment or alleviation of diseases;

b) diagnosis, monitoring, treatment, alleviation or compensation of trauma or disability;

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

d) control of conception process.

22. (amend. – SG 110/08, in force from 21.03.2010) "Device intended for clinical testing" means any medical device referred to in Art. 2, para 1, items 2 and 3, intended to be used by a medical specialist or by another specialist, having relevant for the testing purposes qualification, for conducting clinical testing in the medical establishment in order to achieve the objective referred to in Art. 32.

23. (amend. – SG 110/08) "Custom-made device" means any medical device referred to in Art. 2, para 1, items 2 or 3, specifically made in accordance with a written prescription by a medical expert or a person with relevant professional qualification, which gives, under his/her responsibility, specific design characteristics of the device and is intended to be used only for an individual named patient.

Mass-produced devices, adapted in order to meet the specific requirements of the medical practitioner or of any other trained user are not considered to be custom-made devices.

24. "Multi-centre clinical trial" means a clinical trial conducted according to a single trial plan but at more than one investigation centre/medical establishment, and therefore by more than one investigator. The investigation centres may be located in the territory of a single Member State, in a number of Member States and/or in Member States and third countries;

25. "Observer" means a person, appointed by the assignor, monitoring whether the clinical investigation at each of its stages is being conducted, recorded and reported according to the protocol, the standard operative procedures, the Good Clinical Practice and the applicable control requirements.

26. "A person independent from the assignor" is a natural person acquainted with the characteristics and the operation of the medical device – subject to a clinical investigation, and with the methodology of conducting such, and who is financially independent from the assignor.

27. "Clinical trial plan" is a document providing information on the purposes, design, methodology, statistical methods and organization of a clinical investigation.

28. "Intended purpose" means the use for which a medical device has been designated according to the data provided by the manufacturer on its label, the instructions for use and/or the advertisement notices.

29. "Accessory" means an Art. which, whilst not being a medical device, is intended specifically by its manufacturer to be used together with a device to enable that device to be used in accordance with its intended purpose.

For the purposes of this definition, invasive sampling devices or those which are directly applied to the human body for the purpose of obtaining a specimen within the meaning of Directive

93/42/EEC shall not be considered to be accessories to in vitro diagnostic medical devices;

30. "Manufacturer" means the natural or legal person who:

a) is responsible for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party;

b) (amend. – SG 11/08) assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as devices with a view to their being placed on the market under his own name.

Natural or legal persons who assemble or adapt devices already on the market to their intended purpose for an individual patient shall not be considered manufacturers within the meaning of this Law.

31. "Putting into service" means the stage at which a device has been made available to the final user as being ready for use in a Member State or a state from the European Economic Area for the first time for its intended purpose. An active implantable medical device shall be considered put into service when made available to a qualified expert for implanting.

32. "Placing on the market" means the first making available in return for payment or free of charge of a device, other than a medical device for clinical trial and a device intended for performance evaluation, with a view to distribution and/or use on the territory of the European Union or the European Economic Area, regardless of whether it is new or fully refurbished.

33. "Serious health damage" means:

1. life-threatening condition, illness or harm;

2. lasting harm to the life functions or to a human organ or tissue;

3. a condition which requires medical or surgical intervention in order to prevent the damages under item 2;

34. "Human specimen receptacles" are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination.

35. "Essential amendment in the clinical trial plan" means any amendment in the plan and/or the information contained in the documentation that goes along with it, which affects:

a) the safety or the physical and mental integrity of the persons involved;

b) the scientific value of the investigation;

c) the conducting or organization of the trial.

36. "Retail trade" are all activities related to acquisition, storage and sale of medical devices to end users at pharmacies, drugstores or in the sites as per Art. 83, para 2.

37. "Wholesale trade" are all activities related to acquisition, storage, import of medical devices intended for sale, except retail trade.

38. (amend. – SG 110/08) "Authorised representative" means any natural or legal person established on the territory of a Member State or a state from the European Economic Area who, explicitly authorized by the manufacturer to act on his/her behalf and for his/her account before regulatory bodies of the Member States or the regulatory bodies of the states of the European Economic Area for the fulfillment of manufacturer's obligations under this Law.

§ 2. (amend. – SG 110/08, in force from 21.03.2010) This Law introduces the requirements of Directive 90/385/EEC of the Council of 20 July 1990 on the approximation of the legislation of Member States relating to active implantable medical devices, last amended with Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending the Directive 90/385/EEC of the Council on the approximation of the legislation of Member States relating to active implantable medical devices, of Directive 93/42/EEC of the Council concerning the medical devices and of Directive 98/8/EC concerning the placing on the market of biocidal products (OJ, L 247/21 of 21 September

2007), of Directive 93/42/EEC of the Council of 14 June 1993 of medical devices, last amended by Directive 2007/47/EC of the European Parliament and of the Council and of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, last amended by Regulation (EC) No. 1882/2003 of the European Parliament and of the Council of 29 September 2003 adapting to the Council Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in instruments subject to the procedure referred to in Art. 251 of the EC Treaty.

§ 3. (1) Names and registration numbers of harmonized European standards and the monographs of the European pharmacopoeia for medical devices are published in the Official Journal of EU.

(2) Harmonized European Standards are introduced identically through publishing the text of the standard in Bulgarian language or confirming their application as a Bulgarian Standard pursuant to the Law of National Standardisation.

(3) Names and registration numbers of the Bulgarian standards introducing the harmonized European standards are published in the official bulletin of the State Agency for Metrology and Technical Surveillance and upon publishing it is obligatory that reference to the relevant regulation under Art. 18 is indicated.

§ 4. (1) The general technical specifications determine the requirements for assessment and re-assessment of service, placing on the market and/or putting into service of batches, referent methods and referent materials regarding in-vitro diagnostic medical devices.

(2) The general technical specifications are published in the Official Journal of the EU.

### **Transitional and concluding provisions**

§ 5. (1) Traders, who have been authorized to carry out wholesale trade in medicines - medical devices, the authorization being issued after December 29, 2002 pursuant to the repealed Law for the Medicines And Pharmacies for the Human Medicine, shall, within three months from the entry into force of the Law, submit an application form for entry ex officio in the register as per Art. 81, to which shall be attached the documents under Art. 78, para 1, items 1 and 2, para 2, items 3 and 4, as well as a statement that there is a change in the address of the storage and trade premises.

(2) Within 30 days from the submission of the documentation under para 1 the executive director of BDA shall issue an authorization for wholesale trade in medical devices.

(3) By granting the authorization under para 2 the wholesale trade permission issued pursuant to the repealed Law for the Medicines and Pharmacies for the Human Medicine shall be considered annulled.

§ 6. Traders, who have obtained authorization for wholesale trade in medicines without time limit, issued after December 29, 2002 pursuant to the repealed Law for the Medicines And Pharmacies for the Human Medicine, shall submit an application along with the required documents for obtaining authorization for wholesale trade in medical products pursuant to the present Law by 31 December 2007.

§ 7. Traders, who have obtained authorization for wholesale trade in medicines without time limit, issued after December 29, 2002 pursuant to the repealed Law for the Medicines And Pharmacies for the Human Medicine, shall submit an application along with the required documents for obtaining



authorization for wholesale trade in medical products pursuant to the present Law by 31 December 2007.

§ 8. Applications for granting authorization for wholesale trade in medical devices, which have been submitted before the entry into force of this Law shall be considered and completed under the terms and following the procedure provided by it.

§ 9. (1) Authorizations for use issued pursuant to the repealed Law for the Medicines And Pharmacies for the Human Medicine, shall be considered annulled from the date of entry into force of the present Law.

(2) Manufacturers of medical devices as per Art. 29, paras 1 and 2, whose authorizations have been annulled according to para 1, shall submit notifications in a form to the executive director of BDA within three months from entry into force of this Law.

§ 10. The quantities of medical devices available, whose conformity with the essential requirements as per Directives 90/385/EEC, 93/42/ EC и 98/79/EC at wholesale trade warehouses, pharmacies, drugstores, optics and other commercial sites can be sold for one-year period from the entry into force of the present Law.

§ 11. Medical devices shall be manufactured, stored and renewed as a state reserve and war-time reserves under the terms and following the procedure of the Law of the State Reserves and the War Time Reserves and the acts for its implementation.

§ 12. The Council of Ministers shall make amendments in the structural regulations of BDA and the State Agency for Metrology and Technical Surveillance in three-months term from the promulgation of this Law in the State Gazette.

§ 13. By-laws related to implementation of the Law shall be issued within six months from the date of promulgation of this Law in the State Gazette.

§ 16. The Law shall enter into force from the date of its promulgation in the State Gazette, except for the provisions of Art. 4, para 2, which shall enter into force from 29 December 2009.

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This Law has been passed by the 40th National Assembly on 29 May 2007 and has been affixed by the official seal of the National Assembly.

**Concluding provisions**  
**TO THE LAW FOR AMENDMENT AND SUPPLEMENTATION OF THE LAW FOR THE**  
**MEDICAL DEVICES**

(PROM. – SG 110/08)

§ 51. The Council of Ministers within 6 months after entering of this law into force shall adopt the ordinance referred to in Art. 30a, par. 2.

§ 52. The Minister of Health within two months after entering of this law into force shall adopt the ordinance referred to in Art. 32a.

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§ 54. The provisions of § 1, item 1, § 2, 5, 8, 10, 15, § 16 , item 3, 4 and 5, § 17, 18, 20, 21, 22,

23, 24, 25, 26, 27, 31, 45, 47 and § 50, item 1, items "a", "b", "c" and item 2 shall enter into force from 21 March 2010.

**Transitional and concluding provisions**  
**TO THE LAW ON AMENDMENT AND SUPPLEMENTATION OF THE LAW OF HEALTH**

(PROM. – SG 41/09, IN FORCE FROM 02.06.2009).

§ 96. The Law shall enter into force from the date of its promulgation in the State Gazette, except for:

1. paragraphs 3, 5, 6 and 9, which shall enter into force from January the 1st 2009;
2. paragraphs 26, 36, 38, 39, 40, 41, 42, 43, 44, 65, 66, 69, 70, 73, 77, 78, 79, 80, 81, 82, 83, 88, 89 and 90, which shall enter into force from July 1st 2009;
3. paragraph 21, which shall enter into force from June 1st 2010.

**Transitional and concluding provisions**  
**TO THE LAW ON AMENDMENT AND SUPPLEMENTATION OF THE LAW FOR**  
**TOURISM**

(PROM. – SG 82/03, IN FORCE FROM 16.10.2009)

§ 59. This Law shall enter into force from the date of its promulgation in the State Gazette.

**Appendix to Art. 15, para 1**

