Translation from Bulgarian

ORDINANCE ON THE ESSENTIAL REQUIREMENTS AND THE PROCEDURES FOR CONFORMITY ASSESSMENT TO THE ESSENTIAL REQUIREMENTS FOR MEDICAL DEVICES REFERRED TO IN ARTICLE 2, PARAGRAPH 1 (3) OF THE LAW ON MEDICAL DEVICES

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CHAPTER I
GENERAL PROVISIONS

Article 1. This ordinance defines:

1. The essential requirements for the medical devices referred to in Article 2, paragraph 1 (3) of the Law on Medical Devices;
2. The procedures for conformity assessment to the essential requirements and the technical documentation;
3. The requirements for the notified bodies;
4. The requirements for conducting a risk analysis and risk management procedure for medical devices manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissue;
5. The rules for classification of medical devices referred to in paragraph 1 above.

Article 2. (1) This ordinance applies to:

1. The devices referred to in Article 2, paragraph 1 (3) of the Law on Medical Devices;
2. The devices referred to in paragraph 1 above which are custom-made;
3. The devices referred to in paragraph 1 above intended for clinical investigations;
4. The devices referred to in paragraph 1 above which incorporate, 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 the Medicinal Products in Human Medicine, and which is liable to act upon the body with action ancillary to that of the device;

5. The medical devices under paragraph 1 above which incorporate, as an integral part, a substance derived from human blood or plasma which, if used separately, may be considered to be a medicinal product ingredient or as a medicinal product within the meaning of the Law on the Medicinal Products in Human Medicine, and which is liable to act upon the body with action ancillary to that of the device;
6. The devices referred to in paragraph 1 above which are used for administering medicinal products;
7. Accessories within the meaning of the Law on Medical Devices;
8. Systems or sets of medical devices referred to in paragraph 1;
9. The devices referred to in paragraph 1 manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissue.

(2) Animal tissue originating from bovine, ovine and caprine species, as well as deer, elk, mink, and cats, may be used in the manufacturing of the devices referred to in paragraph 1 (9) intended to come into contact with the human body, excluding those which come into contact with intact skin, in compliance with the requirements specified in Article 23, Article 59, paragraph 2, and Article 66.

(3) The products obtained from an animal tissue by a manufacturing process, such as collagen, gelatin, and tallow, used in the devices referred to in paragraph 1 (9) above, intended to come into contact with the human body, must be derived from by-products meeting the requirements from Article 6, paragraph 1 (c) of Regulation (EC) № 1774/2002 of the European Parliament and the Council laying down health rules concerning animal by-products not intended for human consumption (OJ, L 273, 10 October 2002, pp. 1-95).

Article 3. (1) This ordinance does not apply to:

1. In vitro diagnostic medical devices;
2. Active implantable medical devices;

3. Medicinal products within the meaning of the Law on the Medicinal Products in Human Medicine;
4. Medical devices referred to in Article 2, paragraph 1 (4), which are incorporated in medicinal products and are intended by the manufacturer for single use and only in the form they are;

(2) In the cases specified in Article 1, paragraph 4, the device must meet the requirements of the Law on the Medicinal Products in Human Medicine. The essential requirements defined in the ordinance apply only in terms of the features related to the safe operation of the device.

Article 4. The medical devices specified in Article 2, other than the ones intended for clinical investigations, and the ones which are custom-made, shall be placed on the market and/or put into service only after they obtain a CE marking certifying that their conformity to the essential requirements from chapter two has been assessed following the applicable procedures from chapter three.

Article 5. The medical devices specified in Article 2, paragraph 1 (2) shall be put into service only if they conform to the requirements of chapter one, section III of the Law on Medical Devices.

Article 6. The medical devices specified in Article 2, paragraph 1 (3) shall be provided for clinical investigation to an investigator in compliance with the requirements laid down in chapter three, section II of the Law on Medical Devices.

Article 7. The medical devices specified in Article 2, paragraph 1 (8) shall be placed on the market and/or put into service only after they conform to the requirements laid down in chapter one, section IV of the Law on Medical Devices.

Article 8. (1) It is assumed that the medical devices specified in Article 2 designed and manufactured in compliance with the Bulgarian standards introducing the harmonized European standards published in the Official Journal of the European Union conform to the essential requirements of chapter two.

(2) It is assumed that the medical devices specified in Article 2 (for example the surgical sutures and the devices specified in Article 2, paragraph 1 (4) and (5), when there is interaction between medicinal products and the materials used in devices) designed and manufactured in compliance with specific monographs of the European Pharmacopoeia conform to the essential requirements of the ordinance.

Article 9. The classification of the medical devices specified in Article 2, paragraph 1 (1) into Classes I, IIa, IIb and III is made according to Annex VIII.

CHAPTER II
ESSENTIAL REQUIREMENTS FOR THE MEDICAL DEVICES SPECIFIED IN ARTICLE 2

Section I
General Requirements

Article 10. (1) (Supplemented SG issue 106 of 2008, effective as of 21 March 2010) The device must be designed and manufactured in such a way that when used under the conditions and for the purposes it is intended for, it will not compromise the safety and health of the patients, the users or third parties.

(2) (Supplemented SG issue 106 of 2008, effective as of 21 March 2010) In all cases specified in paragraph 1 above the benefits to the patient must be greater than the expected risks, and the risk-benefit ratio must ensure a high level of protection of health and safety.

(3) (New – SG issue 106 of 2008, effective as of 21 March 2010) The requirement under paragraph 2 above includes:

1. Reducing, as much as possible, the risks of mistakes related to the use of the device and resulting from the ergonomic features of the device and the conditions of the environment where it is intended to be used, and

2. Evaluating the technical knowledge, experience, education and training, and if possible, the health and physical condition of the user of the device.

Article 11. (1) The solutions adopted by the manufacturer for the design and construction of the medical devices must conform to the safety principles and to the state-of-the-art technology.

(2) In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:

1. To eliminate or reduce risks as far as possible (safe design and construction)
2. Where risks cannot be eliminated, to take adequate protection measures, including alarms;
3. To inform users of the residual risks that have not been eliminated despite the adopted protection measures.

Article 12. The medical devices must achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the following functions:

1. Diagnosis, prevention, monitoring, treatment or alleviation of disease;
2. Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
3. Investigation, replacement or modification of the anatomy or of a physiological process;
4. Control of conception.

Article 13. The medical devices must be designed and manufactured in such a way that during their lifetime, as indicated by the manufacturer, their characteristics and performances will not be adversely affected to such a degree that the safety and health of the patients, the users or third parties are compromised when the device is subjected to the stresses which can occur during normal conditions of use.

Article 14. The medical devices must be designed, manufactured and packaged in such a way that their characteristics and performances will not be adversely affected during transport and storage, provided that the manufacturer's instructions are fully complied with.

Article 15. Any undesirable side effects of the use of the medical device must constitute an acceptable risk when weighted against the intended performance.

Article 15a. (New – SG issue 106 of 2008, effective as of 21 March 2010) When establishing the compliance of the device with the essential requirements, the data from the clinical assessment must also be included as provided for in chapter three of the Law on Medical Devices.

Section II
Design and Construction
Chemical, physical and biological properties

Article 16. The medical devices must be designed and manufactured in such a way as to conform to their intended purpose and meet the requirements specified in Section I. Particular attention must be paid to:

1. the type of materials used, particularly as regards toxicity and flammability;
2. the compatibility between the materials used and the biological tissues, cells, and body fluids
3. (New – SG issue 106 of 2008, effective as of 21 March 2010) Where appropriate, the results of the biophysical studies which have been validated.

Article 17. (1) The medical devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices (including to the patients).

(2) Particular attention must be paid to the tissues exposed and the duration and frequency of the exposure.

Article 18. (1) The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they come into contact during their normal use or during routine procedures.

(2) If the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned, and the performance of the medicinal products, according to their intended use, must not be affected by the device.

Article 19. (1) In the case of the medical devices specified in Article 2, paragraph 1 (4) or (5) the substance which is considered as a medicinal product, or the medicinal product, derived from human blood or human plasma, must comply with the requirements for quality, safety and efficiency in compliance with the Law on the Medicinal Products in Human Medicine.

(2) (Amended SG issue 106 of 2008, effective as of 21 March 2010) The notified body under Article 64, paragraph 2 or Article 65 of the Law on Medical Devices, having justified the need of incorporating the substance in the medical device under Article 2, paragraph 1 (4) taking into account its intended purpose, shall require a statement from a regulatory body of a EU Member State or of the European Medicines Agency (EMA) for the quality and safety of the substance, as well as a clinical assessment of the risk-benefit ratio related to its incorporation in the device under paragraph 1. To produce a statement, the regulatory body of the Member State or EMA must take into account the manufacturing process and the data justifying the benefits of the incorporation of the substance in the device provided by the notified body.

(3) (Amended SG issue 106 of 2008, effective as of 21 March 2010) In the cases of devices listed in Article 2, paragraph 1 (5), the statement specified in paragraph 2 is produced by EMA.

(4) (Amended SG, issue 106 of 2008, effective as of 21 March 2010) If there are changes in the substance specified in paragraph 1, which most often result from the

manufacturing process, the manufacturer must inform the notified body to that effect. The notified body must require a statement from the respective regulatory body under Article 2 or from EMA, on the quality and safety of the changed substance.

(5) (New – SG issue 106 of 2008, effective as of 21 March 2010) (1) The respective regulatory body or EMA must issue a scientifically grounded prescription to the notified body when they receive information that the ancillary substance incorporated in the device according to Article 19, paragraph 1, could affect the established risk-benefit ratio.

(2) In the cases under paragraph 1 the notified body decides whether a second conformity assessment must be carried out for the device following the applicable procedures.

Article 20. (Amended SG issue 106 of 2008, effective as of 21 March 2010) (1) The medical devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device when these substances are unrelated to the intended purpose of the device. Special attention shall be given to substances which are classified as carcinogenic, mutagenic or toxic to reproduction, in accordance with the Ordinance on the administrative provisions relating to the classification and packaging of chemical substances and preparations (Promulgated in SG issue 5 of 2003; Modified and supplemented in issue 66 of 2004, issue 50 and 57 of 2005, issue 20 of 2007 and issue 4 and 51 of 2008).

(2) If a device, or any part of it, is intended to administer and/or remove medicines, body liquids or other substances to or from the body, or a device intended for transport and storage of such fluids or substances, contains phthalates classified as carcinogenic, mutagenic or toxic to reproduction of category 1 or 2, in accordance with the ordinance specified in paragraph 1 above, the device and/or the packaging for each unit or, where appropriate, the sales packaging, must bear a symbol indicating that the device contains phthalates.

(3) In the cases when a device containing the substances specified in paragraph 1 or 2 above is intended for treatment of children, pregnant or nursing women, the manufacturer must include in the technical documentation a justification for using such substances in accordance with the essential requirements. The instructions for use must provide information on the residual risks and, if applicable, on appropriate precautionary measures.

Article 21. Devices must be designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.

Section III
Infection and microbial contamination

Article 22. (1) The medical devices must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties.

(2) The medical devices must be designed in such a way as to allow easy handling and, at the same time, minimize contamination of the device by the patient or vice versa during use.

Article 23. (1) Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance in accordance with the Veterinary Medicine Act, adapted to the intended use of the tissues in the devices.

(2) The notified bodies specified in Article 64, paragraph 2 or Article 65 of the Medical Device Act shall retain information on the geographical origin of the animals.

(3) Processing, preservation, investigation and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. Safety with regard to viruses and other transferable agents must be insured by implementation of validated methods of viral inactivation or elimination in the course of the manufacturing process.

Article 24. (1) Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when transported, stored and placed on the market and remain sterile until the protective packaging is damaged or opened.

(2) Medical devices delivered in a sterile state to be placed on the market and/or put into service, must be manufactured and sterilized by appropriate validated methods.

(3) Medical devices intended to be sterilized must be manufactured in appropriately controlled conditions,

Article 25. (1) Packaging systems for non-sterile devices must insure such level of cleanliness that the risk of microbial contamination is reduced to a minimum.

(2) If the devices are to be sterilized prior to use, the risk of microbial contamination must be reduced to a minimum.

(3) The packaging system specified in paragraph 2 above must be suitable for the device taking account of the method of sterilization indicated by the manufacturer.

Article 26. The packaging and/or labels of the medical device must distinguish between identical or similar products sold in both sterile and non-sterile condition.

Section IV
Construction and Environmental Properties

Article 27. If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the device. Any restrictions on use must be indicated on the label and/or in the instructions for use.

Article 28. The medical devices must be designed and manufactured in such a way as to remove or minimize as far as possible:

1. the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;
2. risks connected with reasonably foreseeable environmental conditions (magnetic fields, external electrical influences, electrostatic discharge, temperature or variations in pressure and acceleration);
3. the risks of reciprocal interference with other devices normally used in the investigations or the specific treatment;
4. risks arising where maintenance or calibration are not possible, as with implants, from ageing of materials used or loss of accuracy of any measuring or control medical device.

Article 29. (1) The medical devices must be designed and manufactured in such a way as to prevent the risks of fire or explosion during normal use and in single fault condition.

(2) Particular attention in relation to the requirement under paragraph 1 must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.

Section V
Medical Devices with a Measuring Function

Article 30. (1) The medical devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer.

(2) The measurement and monitoring scale must be designed in line with the ergonomic principles, taking account of the intended purpose of the device.

(3) The measurements made must be expressed in units conforming to the provisions of the Measurements Act.

Section VI
Protection against Radiation

Article 31. The medical devices must be designed and manufactured in such a way that exposure of patients, users and third parties to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

Article 32. Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, the device must be designed and manufactured in such a way as to allow the user to control the emissions.

(2) Such devices as specified in paragraph 1 above shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.

Article 33. Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted with visual displays and/or audible warnings of such emissions.

Article 34. The medical devices must be designed and manufactured in such a way that exposure of patients, users and third parties to the emission of unintended, stray or scattered radiation is reduced as far as possible.

Article 35. The operating instructions for the medical devices emitting radiation must give detailed information on:

1. the nature of the emitted radiation;
2. the means of protecting the patient and the user;
3. the ways of avoiding misuse;
4. the ways of eliminating the risks caused by improper installation.

Article 36. Devices intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended use.

Article 37. Devices emitting ionizing radiation intended for diagnostic radiology must be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.

Article 38. Devices emitting ionizing radiation intended for therapeutic radiology must be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and, where appropriate, the quality of radiation.

Section VII
Medical Devices Connected to or Equipped with an Energy Source

Article 39. Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition in the system appropriate means must be adopted to eliminate or reduce as far as possible consequent risks.

Article 39a. (New – SG issue 106 of 2008, effective as of 21 March 2010) Software included in medical devices, or constituting a medical device itself, must be validated in accordance with the latest technology, taking account of the principles of development of the life cycle, the risk management, validation and confirmation.

Article 40. Devices where the safety of the patients depends on an internal energy source must be equipped with:

1. apparatus monitoring the status of the energy source
2. an alarm system sending alert signals each time there are problems with the state of the power supply

Article 41. Devices intended to monitor the clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.

Article 42. Devices must be designed and manufactured in such a way as to reduce as far as practicable and appropriate the risks of creating electromagnetic interference which could impair the operation of other devices or equipment in the usual environment.

Article 43. Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are properly installed and maintained.

Article 44. Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with the resistance and stability of the moving parts of the device.

Article 45. Devices must be designed and manufactured in such a way as to reduce to the lowest practicable level the risks to the patients and/or users arising from vibration generated by the devices, taking account of technical progress, unless the vibrations are part of the specified performance.

Article 46. Devices must be designed and manufactured in such a way as to reduce to the lowest practicable level the risks to the patients and/or user arising from the noise emitted, taking account of technical progress, unless the noise emitted is part of the specified performance.

Article 47. Devices must be designed constructed in such a way as to minimize all possible risks arising from their connection to sources of electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle.

Article 48. Devices must be designed in such a way as to insure that the accessible parts and their surroundings (excluding the parts intended to supply heat) must not attain potentially dangerous temperatures under normal use.

Article 49. Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the delivered amount can be set and maintained accurately enough to guarantee the safety of the patient and of the user.

Article 50. (1) Devices must be fitted with means of indicating any inadequacies in the delivered amount of energy or substances which could pose a danger to the patient.

(2) Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.

Article 51. (1) The function of the controls and indicators must be clearly specified on the devices.
(2) Where a device bears instructions required for its operation or indicates operating parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.

Section VIII
Information Supplied by the Manufacturer

Article 52. (1) (Supplemented SG issue 106 of 2008, effective as of 21 March 2010) Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and/or knowledge of the potential users, i.e. clinical specialists or patients, and to provide detailed information about the manufacturer.

(2) The information specified in paragraph 1 above comprises the data on the label of the device and in its instructions for use.

(3) The information needed to use the device safely and properly must be set out on the device itself and on the sales packaging, and/or the individual labeling of each unit, if any.

(4) Instructions for use are not needed for medical devices under Article 2, paragraph 1 (1) of Class I and Class IIa, if, according to the manufacturer, they may be used safely without specific instructions for use.

Article 53. (1) The information to be supplied as specified in Article 52 may take the form of symbols.
(2) Any symbol and identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colour used must be described in the documentation supplied with the device.

Article 54. (1) The label must contain the following information:

1. (Amended SG issue 106 of 2008, effective as of 21 March 2010): the name and address of the manufacturer; for devices imported into the European Union from a third country, the label, the outer packaging, or the instructions for use shall contain in addition the name and address of the authorized representative of the manufacturer under Article 10, paragraph 2 of the Law on Medical Devices;

2. the details strictly necessary for the user to identify the device and the contents of the packaging;

3. a statement indicating that the medical device is sterile;

4. where appropriate, the batch code, preceded by the word 'LOT`, or the serial number;

5. an indication of the date by which the device or part of it can be used safely, expressed as the year, the month and the day;

6. in case of active medical devices, the year of their manufacturing which is included in the batch number or the serial number of the device;

7. a statement indicating that the device is a single use device;

8. in case of custom-made devices, the words ‘custom-made device’;

9. in case of devices intended for clinical investigations, the words ‘for clinical investigations only’;

10. any particular storage and/or handling conditions;

11. any particular operating instructions;

12. appropriate warnings and/or precautions to take;

13. where appropriate, the specific sterilization method;

14. in case of devices under Article 2, paragraph 1 (5), it must contain indication that the device contains medicinal product/ingredient of a medicinal product derived from human blood or from human plasma.

(2) The contents of the label under paragraph 1 must also be in Bulgarian when the medicinal product is not intended for professional use.

Article 55. The manufacturer must clearly state the intended purpose on the label and in the instructions for use.

Article 56. Devices and separate components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.

Article 57. The instructions for use must contain the following particulars:

1. The details referred to in Article 54, paragraph 1, with the exception of points 4 and 5;

2. the performances referred to in Article 12 and any undesirable side-effects;

3. if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of their characteristics in order to obtain a safe combination;

4. all the information needed to verify whether the device is properly installed and can operate safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the device operates properly and safely at all times;

5. where appropriate, information to avoid certain risks in connection with implantation of the device;

6. information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment;

7. the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;

8. if the device is reusable:

a) Information on the appropriate processes to allow reuse, including cleaning, disinfection, and packaging;

b) Where appropriate, the method of sterilization of the device when it is intended for reuse;

c) Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Article 10 for devices intended for sterilization before use;

d) The maximum allowed number of reuses.

9. (New – SG issue 106 of 2008, effective as of 21 March 2010) If the device is for single use, information on characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used; in the cases specified in Article 52, paragraph 4, such information is to be provided to the user upon request;

10. (Former paragraph 9 – SG issue 106 of 2008, effective as of 21 March 2010) Details of any further treatment or handling needed before the device can be used, such as sterilization, final assembly, etc.;

11. (Former paragraph 10 – SG issue 106 of 2008, effective as of 21 March 2010) In the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.

Article 58. The instructions for use must also include details allowing the medical staff to brief the patient on any contraindications and any precautions to be taken, as follows:

1. Precautions to be taken in the event of changes in the performance of the device;

2. Precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences or variations in pressure, acceleration, etc.;

3. Information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered;

4. Precautions to be taken against any special, unusual risks related to the device;

5. (Supplemented SG issue 106 of 2008, effective as of 21 March 2010) Information on the active substances or the human blood or human plasma derivatives incorporated into the device as an integral part in accordance with Article 19, paragraph 1;

6. Degree of accuracy claimed for devices with a measuring function;

7. (New – SG issue 106 of 2008, effective as of 21 March 2010) Date of issue or the latest revision of the instructions for use.

Section III
CONFORMITY ASSESSMENT AND VERIFICATION

Article 59. (1) In order to affix the CE marking on a device falling within Class III, other than devices specified in Article 2, paragraph 2 (2) and (3), the manufacturer must apply one of the following assessment procedures:

1. 'Full quality assurance' in accordance with Annex I, or

2. 'EC type-examination' in accordance with Annex II, coupled with:

a) The procedure relating to the EC verification set out in Annex III, or
b) The procedure relating to the Production quality assurance set out in Annex IV

(2) In the case of devices specified in Article 2, paragraph 1 (9), the manufacturer shall, before applying the conformity assessment procedures specified in paragraph 1 above, develop a risk analysis and risk management strategy in relation to transmissible spongiform encephalopathy in accordance with Annex VII.

Article 60. (1) In the case of devices falling within Class IIa, other than devices specified in Article 2, paragraph 1 (2) and (3), the manufacturer shall, in order to affix the CE marking, follow the procedure relating to the EC declaration of conformity set out in Annex VI, coupled with one of the following procedures:

1. The procedure relating to the EC verification set out in Annex III, or

2. The procedure relating to the Production quality assurance set out in Annex IV, or

3. The procedure relating to the Product quality assurance set out in Annex V.

(2) Instead of applying the procedures under paragraph 1 above, the manufacturer may also follow the procedure referred to in Article 61, paragraph 1.

Article 61. In the case of devices falling within Class IIb, other than the devices specified in Article 2, paragraph 1 (2) and (3), the manufacturer shall, in order to affix the CE marking, follow one of the following assessment procedures:

1. 'Full quality assurance' in compliance with Annex I, except for paragraph 4 of this Annex; or

2. 'EC type-examination' in compliance with Annex II, coupled with:

a) 'EC verification' in compliance with Annex III, or
b) 'Production quality assurance' in compliance with Annex IV, or
c) 'Product quality assurance' in compliance with Annex V.

Article 62. In the case of devices falling within Class I, other than the devices specified in Article 2, paragraph 1 (2) and (3), the manufacturer shall, in order to affix the CE marking, follow the procedure 'EC Declaration of conformity' referred to in Annex VI and

draw up the EC declaration of conformity required before placing the device on the market.

Article 63. (Amended SG issue 106 of 2008, effective as of 21 March 2010) The persons specified in Article 22, paragraph 1 of the Law on Medical Devices, who perform sterilization of systems or sets of medical devices, and/or medical devices bearing the CE marking which are designed by the manufacturer to be sterilized before use, in order to place the devices on the market must follow any of the procedures set forth in Annexes I or IV.

Article 64. The manufacturer may instruct his authorized representative as specified in Article 10, paragraph 2, of the Law on Medical Devices, to initiate the procedures for conformity assessment provided for in Annexes II, III and VI, and to draw up any of the documented under chapter one, Section III of the Law on Medical Devices relating to custom-made devices, as well as any of the documents under Article 50, paragraph 2 and Article 56, paragraph 1, of the Law on Medical Devices relating to devices intended for clinical investigations.

Article 65. During the conformity assessment procedure for a device, the manufacturer and/or the notified body under Article 64, paragraph 2 or Article 65 of the Law on Medical Devices, shall take account of the results of any assessment and verification operations which have been carried out in accordance with this ordinance at an intermediate stage of manufacture.

Article 66. (1) In the cases of devices under Article 2, paragraph 1 (9), the notified body under Article 64, paragraph 2 or Article 65 of the Law on Medical Devices within the framework of the conformity assessment procedure shall evaluate the manufacturer's risk analysis and risk management strategy developed according to Article 59, paragraph 2, based on:

1. The information supplied by the manufacturer;

2. The justification for the use of animal tissues or derivatives in the device;

3. The results of elimination and/or inactivation studies or of literature search;

4. The manufacturer's control of the sources of raw materials, finished products and subcontractors.

(2) Notified bodies shall assess and document the need to audit the sites in relation to sourcing, including third party supplies.

(3) Notified bodies shall require from the manufacturer a certificate for the suitability of starting materials in compliance with the applicable monograph 'Products with risk of transmitting agents of animal spongiform encephalopathies' of the European Pharmacopoeia, hereinafter 'TSE Certificate', issued by the European Directorate for the Quality of Medicines.

(4) On the grounds of the assessment specified in paragraphs 1 and 2, the notified body shall prepare a summary assessment report.

(5) Where the manufacturer does not have a TSE certificate, the notified body must submit to the State Agency for Metrology and Technical Surveillance the report prepared by it under Article 4, in electronic form, together with a written application for a statement to be issued by the respective Competent Authorities of the other Member States in relation to the evaluation and conclusions of the manufacturer's risk assessment and risk analysis strategy.

(6) The notified body shall, on the grounds of the statements specified in paragraph 5 obtained within 12 weeks of the application date, adopt a resolution on the issuing of an EC design-examination certificate or an EC type-examination certificate.

Article 67. (1) The notified body may require from the manufacturer, where duly justified, any information or data, which is necessary for establishing and maintaining the attestation of conformity in view of the chosen procedure.

(2) (Amended SG issue 106 of 2008, effective as of 21 March 2010). Decisions taken by the notified bodies in accordance with Article 64, paragraph 2 or Article 65 of the Law on Medical Devices where Annexes I, II, IV, and V apply, shall be valid for a maximum of 5 years and may be extended on application, made at a time agreed in the contract under Article 11, paragraph 4 of the Law on Medical Devices, for a further period of 5 years.

Article 68. The records and correspondence relating to the procedures referred to in Articles 59-64 and 66, shall be in Bulgarian or in the official language of the Member State in which the procedures are carried out or in another language acceptable to the notified body.

CHAPTER IV
CRITERIA FOR DESIGNATION OF NOTIFIED BODIES

Article 69. (1) The body specified in Article 61, paragraph 1 of the Law on Medical Devices, applying for permission to carry out conformity assessment of devices under Article 2, paragraph 1, must comply with the requirements of the national standards of the Member States introducing the harmonized European standards EN 45011, EN 45012 and EN ISO/IEC 17025, depending on the procedures and products for which it applies, and:

1. To be able to carry out one or more conformity assessment procedures for medical devices under Article 2, paragraph 1;

2. To use specific methods and instructions for investigation of medical devices when the standards or monographs are not applied;

3. To use a quality system manual and procedures.

(2) The body specified in Article 61, paragraph 1 of the Law on Medical Devices, applying for permission to carry out conformity assessment of devices under Article 2, paragraph 1 (9), must be properly qualified in order to:

1. Identify and assess the potential risks associated with the use of animal tissues and derivatives in the manufacturing of certain devices;

2. Evaluate the manufacturer's risk analysis and risk management strategy related to the risks of transmissible spongiform encephalopathies under Article 59, paragraph 2.

Article 70. (1) The body specified in Article 69 must submit to the chairman of the State Agency for Metrology and Technical Surveillance the documents under Article 61, paragraph 3 of the Law on Medical Devices.

(2) In the cases under Article 61, paragraph 4 of the Law on Medical Devices, the body must submit to the chairman of the State Agency for Metrology and Technical Surveillance an accreditation certificate issued by an accreditation body from a Member State participating in a European accreditation organization, having signed a Multilateral Agreement (MLA) in the specific areas depending on the devices and the procedures for which it applies:

1. 'Full conformity assessment' (Annex I) in compliance with standard EN 45012;

2. 'EC type-examination' (Annex II) in compliance with standards EN 45011 and EN ISO/IEC 17025;

3. 'EC verification' (Annex III) in compliance with standards EN 45011 and EN ISO/IEC 17025, and for devices which are placed on the market in sterile packaging, with standard EN 45012 as well;

4. 'Production quality assurance' (Annex IV) in compliance with standard EN 45012;

5. ‘Product quality assurance’ (Annex V) in compliance with standard EN 45012;

(3) The documents under paragraph 1 or 2 must be accompanied by a reference table containing the types of medical devices, the essential requirements which apply to them, the harmonized standards and monographs, or the methods and instructions on the measurements and investigating procedures which will be followed during conformity assessment.

Additional Provisions

§1. For the purposes of this ordinance:

1. ‘Cell’ means the smallest organised unit of any living form which is capable of independent existence and of replacement of its own substance in a suitable environment;

2. ‘Tissue’ means an organisation of cells and/or extra-cellular constituents;

3. ‘Derivative’ means a material obtained from an animal tissue by a manufacturing process such as collagen, gelatine, monoclonal antibodies;

4. ‘Non-viable’ means having no potential for metabolism or multiplication;

5. ‘Transmissible agents’ means unclassified pathogenic entities, prions and such entities as bovine spongiform encephalopathies agents and scrapie agents;

6. ‘Reduction, elimination or removal" means a process by which the number of transmissible agents is reduced, eliminated or removed in order to prevent infection or pathogenic reaction;

7. ‘Inactivation’ means a process by which the ability to cause infection or pathogenic reaction by transmissible agents is reduced;

8. ‘Source country’ means the country in which the animal was born, has been reared and/or has been slaughtered;

9. ‘Starting materials’ means raw materials or any other product of animal origin out of which, or with the help of which, the devices referred to in Article 2, paragraph 1 (9) are produced;

10. ‘A hip, knee or shoulder replacement’ means an implantable component part of a total a total joint replacement system which is intended to provide a function similar to that of either a natural hip joint, a natural knee joint or a natural shoulder joint. Ancillary components – screws, wedges, plates and instruments – are excluded from this definition.

11. ‘Adverse side effect’ is any undesirable or unforeseeable response to the medical device under normal conditions of use in compliance with the instructions supplied by the manufacturer, including as a result of any deficiencies or inadequacies in the instructions for use, and any event which is the user’s fault.

12. (New SG issue 106 of 2008, effective as of 21 March 2010) ‘Device subcategory’ is a set of devices having common areas of intended use or common technology.

13. (New SG issue 106 of 2008, effective as of 21 March 2010) ‘Generic device group’ is a set of devices having the same or similar intended uses or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics.

14. (New SG issue 106 of 2008, effective as of 21 March 2010) ‘Single-use medical device’ is a device intended for use on one patient during a single procedure.

§2. (Amended SG issue 106 of 2008, effective as of 21 March 2010) This ordinance introduces the provisions of Council Directive 93/42/EEC concerning medical devices (OJ Special issue 2007, chapter 13, volume 11), as last amended by Directive 2007/47/EC (OJ, L 247 of 21 September 2007, pp. 21 – 55), Commission Directive 2003/12/EC on the reclassification of breast implants in the framework of Directive 93/42/EEC (OJ Special issue 2007, chapter 13, volume 39), Commission Directive 2003/32/EC introducing detailed specifications as regards the requirements laid down in Directive 93/42/EEC concerning medical devices manufactured utilising tissues of animal origin (OJ Special issue 2007, chapter 15, volume 9) and of Commission Directive 2005/50/EC on the reclassification of hip, knee and shoulder joint replacements in the framework of Directive 93/42/EEC (OJ Special issue 2007, chapter 13, volume 49).

TRANSITIONAL AND FINAL PROVISIONS

§3. (1) The hip, knee and shoulder replacements for which the conformity assessment procedure under Article 61, paragraph 1, was applied, or according to the national legislation of the other Member States introducing Article 11, paragraph 3, letter 'a' of Council Directive 93/42/EEC concerning medical devices (OJ, L 169 of 12 July 1993, p. 1-43) before 1 September 2007:

1. shall be subject to a complementary conformity assessment under paragraph 4 'EC design examination' of Annex I or pursuant to the national legislation of the other Member States introducing paragraph 4 of Annex II to Directive 93/42/EEC, before 1 September 2009;

2. may be placed on the market and put into service as Class IIb before 1 September 2009;

(2) Regardless of the provisions of paragraph 1 above, the manufacturer may apply the procedure under Article 59, paragraph 1 (2) or according to the legislation of the other Member States introducing Article 11, paragraph 1, letter 'b' of Directive 93/42/EEC.

(3) As of 1 September 2009 hip, knee and shoulder replacements can be placed on the market and/or put into service upon a conformity assessment procedure carried out as specified in Article 59, paragraph 1 (1) or according to the national legislation of the other Member States introducing Article 11, paragraph 1, letter 'a' of Directive 93/42/EEC.

§4. (1) The hip, knee and shoulder replacements for which the conformity assessment procedure under Article 61, paragraph 2, letter 'c', was applied, or according to the national legislation of the other Member States introducing Article 11, paragraph 3, letter 'b' (iii) of Directive 93/42/EEC before 1 September 2007:

1. shall be subject to a conformity assessment under Article 59, paragraph 1 (2) or pursuant to the national legislation of the other Member States introducing Article 11, paragraph 1, letter 'b' (i) or (ii) of Directive 93/42/EEC, before 1 September 2010;

2. may be placed on the market and put into service as Class IIb before 1 September 2010;

(2) Regardless of the provisions of paragraph 1 above, the manufacturer may apply the procedure under Article 59, paragraph 1 (1) or according to the legislation of the other Member States introducing Article 11, paragraph 1, letter 'a' of Directive 93/42/EEC.

(3) As of 1 September 2010 hip, knee and shoulder replacements can be placed on the market and/or put into service upon a conformity assessment procedure carried out as specified in Article 59, paragraph 1 (2) or according to the national legislation of the other Member States introducing Article 11, paragraph 1, letter 'b' (i) and (ii) of Directive 93/42/EEC.

§5. This ordinance is adopted pursuant to Article 18, paragraphs 1, 2, 3 and 5, and Article 61, paragraph 4 of the Law on Medical Devices.

FINAL PROVISIONS

TO ORDINANCE № 294 OF 4 DECEMBER 2008 CONCERNING THE AMENDMENT AND SUPPLEMENTING OF THE DECREES OF THE COUNCIL OF MINISTERS

(Promulgated in SG issue 106 of 2008, effective as of 21 March 2010)

§5. The ordinance becomes effective as of 21 March 2010.

Annex I to Article 59, paragraph 1 (1), Article 61, paragraph 1 and Article 67, paragraph 2

(Amended SG issue 106 of 2008, effective as of 21 March 2010)

'Full quality assurance'

1. (Amended SG issue 106 of 2008, effective as of 21 March 2010) 'Full quality assurance' is the procedure by which the manufacturer that satisfies the obligations under paragraph 2 insures and declares that the medical devices produced by him satisfy the requirements of the ordinance that apply to them. The manufacturer must affix the CE marking to each device and draw up an EC declaration of conformity. The declaration of conformity must be kept by the manufacturer and it contains information about one or more devices identified by means of product name, product code or other unambiguous reference.

2. The manufacturer must ensure application of the quality system approved for the design, manufacture and final inspection of the devices concerned, as specified in paragraphs 3.3 and 4, and is subject to surveillance as specified in paragraph 5.

3. Quality system

3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body, including:

a) The name and address of the manufacturer and any additional manufacturing site covered by the quality system;
b) Adequate information on the device or device category covered by the procedure;
c) The documentation related to the quality system;
d) A written declaration that no such application has been lodged with any other notified body for the same device-related quality system;
e) An undertaking by the manufacturer to fulfil the obligations imposed by the quality system approved;
f) An undertaking by the manufacturer to keep the approved quality system adequate and efficacious;
g) (Amended SG issue 106 of 2008, effective as of 21 March 2010) An undertaking by the manufacturer to institute and keep up to date a systematic procedure to monitor the safety of devices which have been placed on the market and/or put into service in compliance with chapter seven of the Law on Medical Devices, and will assess clinical data in compliance with chapter three of the Law on Medical Devices, and implement appropriate means to apply any necessary corrective action taking account of the nature of the risks in relation to the product; the manufacturer shall notify the Bulgarian Drug Agency immediately upon receiving an alert signal related to the following incidents / potential incidents:

aa) any malfunction, failure or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to, or might have led to, the death of a patient or user, or to a serious deterioration in his or their state of health;

bb) any technical or medical reason connected with the characteristics or the performance of a device for the reasons referred to in subparagraph (aa) leading to systematic recall of devices of the same type.

3.2. (Amended SG, issue 106 of 2008, effective as of 21 March 2010) Application of the quality system must insure that the devices conform to the provisions of this ordinance which apply to them at every stage, from design to final inspection. All elements, requirements, and provisions adopted by the

manufacturer for his quality system must be documented in a systematic and orderly manner in the form of written policy statements and procedures. This quality system documentation must contain full records of the quality programmes, plans, manuals and records. The quality system includes the documents, data and records from the procedures for control and inspection of the design of the devices, as well as detailed description of:

a) the manufacturer's quality objectives;
b) the organizational structure:
aa) the responsibilities of the managerial staff where quality of manufacture of the devices is concerned;
bb) the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of the design, the product and the control of the devices which fail to conform;

c) the procedures for monitoring and verifying the design of the devices, including the specific documentation, and in particular:

aa) a general description of the device, including any variants planned;

bb) technical design specifications, including the standards and/or monographs under Article 8 that are applied, and the results of the risk analyses; and in the cases when the standards and/or monographs under Article 8 are not applied, description of the decisions taken for fulfilling the essential requirements of the ordinance;

cc) the methods and systematic control and inspection ensuring the quality of the device at the design stage, and in particular:

- if the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device(s) having the characteristics specified by the manufacturer

- information on whether the device incorporates, as an integral part, substances derived from human blood or plasma within the meaning of Article 2, paragraph 1 (4) or (5) and data from the tests on the substance or the medicinal product to assess its quality, safety, and efficiency;

- information on whether the device incorporates as an integral part a substance or a medicinal product derived from human blood or from human plasma within the meaning of Article 2, paragraph 1 (4) and (5) and data from the tests on the substance or the medicinal product to assess its quality, safety and efficiency;

- information on whether the devices is under Article 2, paragraph 1 (9) and all data allowing the assessment of the risk analysis and risk management strategy in compliance with Annex VII;

- the decisions adopted by the manufacturer in accordance with Article 11;

- data from the preclinical investigation;

- data from the clinical investigation of the devices in compliance with chapter three of the Law on Medical Devices;

- design of the label and/or the instructions for use, where appropriate;

d) the inspection and quality assurance techniques at the manufacturing stage and in particular:

aa) the processes and procedures which will be used as regards sterilization, supplies and the specific documentation;

bb) the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;

e) the appropriate tests and investigations to be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible to trace back the calibration during the investigations;

3.3. (Supplemented SG issue 106 of 2008, effective as of 21 March 2010). The notified body must audit the quality system to determine whether it meets the requirements referred to in paragraph 3.2. It must presume that quality systems which implement the relevant harmonized standards conform to these requirements. The assessment team must have at least one member with past experience of assessments of the technology concerned. The assessment procedure must include evaluation, on a representative basis, of the documentation related to the design of the specific device/devices, an inspection of the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers and/or subcontractors. The decision containing the conclusions of the inspection and a reasoned statement shall be notified to the manufacturer.

3.4. The manufacturer must inform the notified body under paragraph 3.3 of any plan for substantial changes to the quality system or the product range covered. The notified body must assess the changes proposed and verify whether they meet the requirements of paragraph 3.2 and then it notifies the manufacturer of its decision containing the conclusion of the inspection and a reasoned statement.

4. Examination of the design of the product

4.1. In addition to his obligations under paragraph 3, the manufacturer must lodge with the notified body an application for examination of the design dossier relating to the device which he plans to manufacture and which falls into the category referred to in paragraph 3.1.

4.2. The application must describe the design, manufacture and performances of the device in question. It must include the documents needed to assess whether the device conforms to the requirements of this ordinance specified in paragraph 3.2, letter 'c'.

4.3. The notified body must examine the application under Article 4.2. If it is incomplete, the notified body may require the application to be completed by tests or proofs of compliance with the requirements of the ordinance.

4.3.1. (Amended SG issue 106 of 2008, effective as of 21 March 2010) In the case of devices referred to in Article 2, paragraph 1 (4), the notified body may require a statement from a regulatory body of a Member State or from EMA in relation to the quality, safety and the clinical assessment of the risk/benefit ratio resulting from the inclusion of a specific substance in the device, and shall take its final decision on the grounds of this statement. The respective regulatory body or EMA must issue such a statement within 210 after the lodging a valid request. The statements of the specific regulatory body shall become an integral part of the documentation of the device. The notified body must inform the respective regulatory body or EMA of its decision.

4.3.2. (Amended SG issue 106 of 2008, effective as of 21 March 2010) In the case of medical devices referred to in Article 2, paragraph 1 (5), the notified body shall request a statement from EMA on the grounds of which it will make its final decision. The European Medicines Agency shall issue a statement within 210 after the lodging of a valid request. The statement shall become an integral part of the documentation of the device. The notified body will give due consideration to the opinion of EMA when making its decision. The

notified body may not deliver the certificate if EMA's scientific opinion is unfavourable. It will convey its final decision to EMA.

4.3.3. When the device conforms to the general requirements of the ordinance, and in the cases under paragraph 4.3.1. and 4.3.2., when the opinion of the regulatory bodies is favourable, the notified body delivers an EC design examination certificate.

4.3.4. In the case of medical devices referred to in Article 2, paragraph 1 (9), the notified body must fulfil its obligations under Article 66.

4.3.5. The certificate must contain conclusions from the tests, the conditions of validity; the data needed for identification of the approved design, and, where appropriate, description of the intended purpose of the device.

4.4. Changes to the approved design must receive further approval from the notified body which issued the EC design examination certificate wherever the changes could affect conformity with the essential requirements or with the conditions prescribed for use of the device. The applicant shall inform the notified body which issued the certificate of any such changes made to the approved design. The additional approval must take the form of a supplement to the EC design examination certificate.

5. Surveillance

5.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality system.

5.2. The manufacturer must allow the notified body access for inspection purposes to the inspection, investigation and storage locations and supply it with all relevant information:

a) the documentation of the quality system;

b) (Amended SG issue 106 of 2008, effective as of 21 March 2010) The data stipulated in the part of the quality system related to design, such as the results of analyses, calculation, tests, decisions adopted under Article 11, data from preclinical and clinical investigations, plans and results from monitoring the device after it is placed on the market, etc.;

c) The data stipulated in the part of the quality system relating to manufacture, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

5.3. The notified body must periodically carry out appropriate inspections and assessments to make sure that the manufacturer applies the approved quality system and must supply the manufacturer with an assessment report.

5.4. In addition, the notified body may pay unannounced visits to the manufacturer during which it may decide to carry out or ask for tests in order to check that the quality system is working properly. It must provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.

6. (Amended SG issue 106 of 2008, effective as of 21 March 2010) The manufacturer or his authorized representative must keep for a period ending at least five years, or in the case of implantable devices, at least fifteen years after the last product has been manufactured, the following documentation and make it available, upon request, to the national authorities referred to in Article 86, paragraph 2 of the Law on Medical Devices:

a) declaration of conformity;
b) the documentation of the quality system and, in particular, the documentation, data and records specified in paragraph 3.2;
c) the documentation under paragraph 3.4;
d) the documentation under paragraph 4.2;

e) the decisions and reports under paragraphs 3.3, 4.3, 4.4, 5.3 and 5.4

7. (Amended SG issue 106 of 2008, effective as of 21 March 2010) Applicability of the 'Full quality assurance' to devices Class IIa and IIb.

7.1. In compliance with Articles 60 and 61, the 'Full quality assurance' procedure may be applied for medical devices falling within Classes IIa and IIb, except for paragraph 4;

7.2. For devices Class IIa, the notified body is required evaluate as part of the assessment under paragraph 3.3. the technical documentation referred to in paragraph 3.2., letter 'c', at least one representative sample of each device subcategory to assess its conformity to the provisions of this ordinance;

7.3. For devices Class IIb, the notified body is required to evaluate as part of the assessment under paragraph 3.3 the technical documentation referred to in paragraph 3.2, letter 'c', at least one representative sample of each generic device group to assess its conformity to the provisions of this ordinance;

7.4. Regarding the choice of representative sample(s), the notified body will consider the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended use and the results of previous relevant assessments (such as physical, chemical and biological properties) in compliance with the requirements of this ordinance.

The notified body must document the collected information, providing a reasoned statement of its choice of sample(s), and upon request must provided it to the State Agency for Metrology and Technical Surveillance.

7.5. Assessment of additional samples is carried out by the notified body as part of the surveillance procedure under paragraph 5.

8. Upon completing the manufacture of each batch of devices referred to in Article 2, paragraph 1 (5), the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by the Bulgarian Drug Agency or a laboratory designated for that purpose by a Member State. This product is an integral part of the device and is liable to act upon the body with action ancillary to that of the device.

Annex II to Article 59, paragraph 1 (2), Article 61, paragraph 2, Article 64 and Article 67, paragraph 2

(Amended SG issue 106 of 2008, effective as of 21 March 2010)

'EC type examination'

1. The 'EC type examination' is the procedure whereby the notified body ascertains that a representative sample of the production covered fulfils the relevant provisions of this ordinance.

2. The notified body must lodge an application for examination of the type with a notified body of his choice, which includes:

a) The name and address of the manufacturer or the name and address of the authorized representative;

b) The documentation described in paragraph 3 needed to assess the conformity of the representative sample of the production in question, hereinafter referred to as the 'type', with the requirements of this ordinance. The manufacturer must make a 'type' available to the notified body. The notified body may request other samples as necessary;

c) A written declaration that no application has been lodged with any other notified body for the same type.

3. The documentation must allow an understanding of the design, the manufacture and the performances of the product and must contain the following items in particular:

a) A general description of the type, including any variants planned;

b) Design drawings, methods of manufacture envisaged, in particular as regards sterilization, and diagrams of components, assemblies, circuits, etc.;

c) The descriptions and explanations necessary to understand the drawings and diagrams referred to in 'b' above, and the operation of the product;

d) A list of the standards and/or monographs referred to in Article 8, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements if the standards referred to in Article 8 have not been applied in full;

e) The results of the design calculations, risk analysis, investigations, etc. carried out;

f) A statement indicating whether or not the device incorporates, as an integral part, a substance or a medical product derived from human blood or human plasma as referred to in Article 2, paragraph 1 (4) or (5), and data on the tests conducted to assess the quality, safety and efficiency of the product taking account of its intended purpose;

g) All data allowing the assessment of the risk analysis and risk management strategy, if the medical devices is under Article 2, paragraph 1 (9);

h) (Amended SG issue 106 of 2008, effective as of 21 March 2010) The decisions adopted by the manufactured under Article 11;

i) (Amended SG issue 106 of 2008, effective as of 21 March 2010) All preclinical data;

j) (New SG issue 106 of 2008, effective as of 21 March 2010) All clinical data related to the devices in accordance with chapter three of the Law on Medical Devices);

k) (New SG issue 106 of 2008, effective as of 21 March 2010) The draft label and, where appropriate, instructions for use.

4. The notified body must:

4.1. Examine and assess the documentation and verify that the type has been manufactured in conformity with that documentation; it must also record the devices designed in conformity with the applicable provisions of the standards and/or monographs referred to in Article 8, as well as the devices not designed on the basis of the relevant provisions of the abovementioned standards and/or monographs.

4.2. Carry out or arrange for the appropriate inspections and the tests necessary to verify whether the solutions adopted by the manufacturer meet the essential requirements of this ordinance, if the standards and/or monographs referred to in Article 8 have not been applied. If the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device(s) having the characteristics specified by the manufacturer.

4.3. Carry out or arrange for the appropriate inspections and the tests necessary to verify whether, if the manufacturer has chosen to apply the relevant standards and/or monographs under Article 8, these have actually been applied.

4.4. Agree with the applicant on the place where the necessary inspections and tests will be carried out.

5. If the type conforms to the provisions of this ordinance, the notified body issues the applicant with an EC type-examination certificate. The certificate must contain the name and address of the manufacturer, the conclusions of the inspection, the conditions of validity and the data needed for identification of the type approved. The relevant parts of the documentation must be annexed to the certificate and a copy kept by the notified body.

5.1. (Amended SG issue 106 of 2008, effective as of 21 March 2010) In the case of devices referred to in Article 2, paragraph 1 (4), the notified body shall, before taking a decision, consult one of the competent bodies established by the Member States or EMA on the quality, safety and clinical assessment of the risk/benefit ratio related to the incorporation of the substance in the device, and shall give due consideration to the views expressed in this consultation when making its decision. The competent body or EMA shall issue their statement within 210 after the lodging of a valid request. The statement of the respective competent body becomes an integral part of the device documentation. The notified body will convey its final decision to the competent body concerned.

5.2. (Amended SG issue 106 of 2008, effective as of 21 March 2010) In the case of devices referred to in Article 2, paragraph 1 (5), the notified body shall request a statement from EMA on the grounds of which it will make its final decision. The European Medicines Agency shall issue a statement within 210 after the lodging of a valid request. The statement shall become an integral part of the documentation of the device. The notified body will give due consideration to the opinion of EMA when making its decision. The notified body may not deliver the certificate if EMA's scientific opinion is unfavourable. It will convey its final decision to EMA.

5.3. In the case of medical devices referred to in Article 2, paragraph 1 (9), the notified body must fulfil its obligations under Article 66.

6. The applicant must inform the notified body which issued the EC type-examination certificate of any significant change made to the approved product which could affect the conformity with the essential requirements or with the conditions prescribed for use of the device. The notified body issues a supplement to the original EC type examination certificate, if it approves the changes.

7. The notified body under paragraph 5 must provide to the other notified bodies a copy of the issued EC type examination certificates and/or their supplements, and must inform the manufacturer accordingly.

8. (Supplemented SG issue 106 of 2008, effective as of 21 March 2010). The manufacturer or his authorized representative must keep for a period ending at least five years, or in the case of implantable devices, at least fifteen years after the last product has been manufactured, the technical documentation and a copy of the CE type-examination certificates, as well as any supplements to them.

Annex III to Article 59, paragraph 1 (2), letter 'a', Article 60, paragraph 1 (1), Article 61, paragraph 2, letter 'a', Articles 63 and 64

(Amended SG issue 106 of 2008, effective as of 2 1March 2010)

'EC Verification'

1. 'EC verification' is the procedure whereby the manufacturer or his authorized representative ensures and declares that the products which have been subject to the procedure set out in paragraph 4 conform to the type described in the EC

type-examination certificate and meet the requirements of this ordinance which apply to them.

2. The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which conform to the type described in the EC type-examination certificate and to the requirements of this ordinance which apply to them. Before the start of manufacture, the manufacturer must prepare documents defining the manufacturing process, in particular as regards sterilization where necessary, together with the technical documentation and all the routine provisions to be implemented to ensure homogeneous production and, where appropriate, conformity of the products with the type described in the EC type-examination certificate and with the requirements of this ordinance which apply to them. The manufacturer must affix the CE marking on the devices and draw up a declaration of conformity.

   In addition, for products placed on the market in sterile condition, and only for those aspects of the manufacturing process designed to secure and maintain sterility, the manufacturer must apply the provisions of Annex IV, paragraphs 3 and 4.

3. (Amended SG issue 106 of 2008, effective as of 21 March 2010). The manufacturer must undertake to institute and keep up to date a systematic procedure to monitor the safety of devices which have been placed on the market and/or put into service in compliance with chapter seven of the Law on Medical Devices, and will assess clinical data in compliance with chapter three of the Law on Medical Devices, and implement appropriate means to apply any necessary corrective action taking account of the nature of the risks in relation to the product; the manufacturer shall notify the Bulgarian Drug Agency immediately upon receiving an alert signal related to the following incidents / potential incidents:

a) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which

might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;

b) any technical or medical reason connected with the characteristics or performance of a device for the reasons referred to in subparagraph (a) leading to systematic recall of devices of the same type

4. The notified body must carry out the appropriate examinations and tests in order to verify the conformity of the product with the requirements of this ordinance either by examining and investigating every product as specified in paragraph 5 or by examining and investigating products on a statistical basis as specified in paragraph 6, as the manufacturer decides.

The aforementioned checks do not apply to those aspects of the manufacturing process designed to secure sterility.

5. Verification by examination and investigation of every product:

5.1. Every product is examined individually and the appropriate tests defined in the relevant standards and/or monographs referred to in Article 8 or equivalent tests must be carried out in order to verify the conformity of the products with the EC type described in the type-examination certificate and with the requirements of this ordinance which apply to them.

5.2. The notified body must affix, or have affixed its identification number to each approved product and must draw up a written certificate of conformity relating to the tests carried out.

6. Statistical verification

6.1. For a statistical verification, the manufacturer must present the manufactured products in the form of homogeneous batches and to take all necessary measures to ensure that the manufacturing process provides homogeneity to each manufactured batch.

6.2. Random samples are taken from each batch and examined individually by the notified body by appropriate tests defined in the relevant standards and/or monographs referred to in Article 8, or equivalent tests must be carried out to verify the conformity of the products with the type described in the EC type-examination certificate and with the requirements of this ordinance which apply to them in order to determine whether to accept or reject the batch.

6.3. (Amended SG issue 106 of 2008, effective as of 21 March 2010) Statistical control of the products will be based on attributes and variables, entailing sampling schemes with operational characteristics which ensure a high level of safety and performance according to the state of the art. The sampling scheme will be established by the harmonised standards and/or monographs referred to in Article 8, taking account of the specific nature of the product categories in question.

6.4. If the batch is accepted, the notified body affixes or has affixed its identification number to each product and draws up a written certificate of conformity relating to the tests carried out. All products in the batch may be put on the market except any in the sample which failed to conform.

If a batch is rejected, the competent notified body must take appropriate measures to prevent the batch from being placed on the market. In the event of frequent rejection of batches, the notified body may suspend the statistical verification.

The manufacturer may, on the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

7. (Supplemented SG issue 106 of 2008, effective as of 21 March 2010) The manufacturer or his authorized representative must keep for a period ending at least five years, or in the case of implantable devices, at least fifteen years after the last product has been manufactured, the following documentation and

make it available, upon request, to the national authorities under Article 86, paragraph 2 of the Law on Medical Devices:

a) declaration of conformity;
b) the documentation referred to in paragraph 2;
c) the certificates referred to in paragraph 5.2 and 6.4;
d) where appropriate, the EC type-examination certificate in accordance with Annex II

8. (Amended SG issue 106 of 2008, effective as of 21 March 2010) In line with Article 60, the 'EC verification' procedure may apply to products in Class IIa, provided that the following requirements are complied with:

8.1. In derogation from paragraphs 1 and 2, by virtue of the declaration of conformity the manufacturer ensures and declares that the products in Class IIa are manufactured in conformity with the technical documentation referred to in paragraph 3 of Annex VI and meet the requirements of this ordinance which apply to them.

8.2. In derogation from paragraphs 1, 2, 5 and 6, the notified body confirms the conformity of the products in Class IIa with the technical documentation referred to in paragraph 3 of Annex VI.

9. Upon completing the manufacture of each batch of devices referred to in Article 2, paragraph 1 (5) and in the case of statistical verification referred to in paragraph 6, the manufacturer shall inform the notified body of the release of each batch of devices and send to it the official certificate concerning the release of the batch of human blood or human plasma derivative used in the device, issued by the Bulgarian Drug Agency or a laboratory designated for that purpose by a Member State. This product is an integral part of the device and is liable to act upon the body with action ancillary to that of the device.

Annex IV to Article 59, paragraph 1 (2b), Article 60, paragraph 1 (2), Article 61 (2b) and Article 63

(Amended SG issue 106 of 2008, effective as of 21 March 2010)

'Production quality assurance'

1. The manufacturer must ensure application of the quality system approved for the manufacture of the products concerned and carry out the final inspection, as specified in paragraph 3, and is subject to the surveillance referred to in paragraph 4.

2. (Amended SG issue 106 of 2008, effective as of 21 March 2010) 'Production quality assurance' is a procedure whereby the manufacturer who satisfies the obligations of paragraph 1 ensures and declares that the devices concerned are in conformity with the type described in the EC type-examination certificate and satisfy the requirements of this ordinance which apply to it.

   The manufacturer must affix the CE marking to each device and draw up a written declaration of conformity. This declaration must cover one or more medical devices clearly identified by a name, code or other accompanied by means of product name, product code or other unambiguous reference. The declaration of conformity must be kept by the manufacturer.

3. Quality system

3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body, which includes:

a) the name and address of the manufacturer;
b) all the relevant information on the product or product category covered by the procedure;
c) the documentation on the quality system;

d) a written declaration that no application has been lodged with any other notified body for a quality system covering the same products;
e) an undertaking to fulfil the obligations imposed by the approved quality system;
f) an undertaking to maintain the practicability and effectiveness of the approved quality system;
g) where appropriate, the technical documentation on the types approved and a copy of the EC type-examination certificate;
h) (Amended SG issue 106 of 2008, effective as of 21 March 2010) An undertaking by the manufacturer to institute and keep up to date a systematic procedure to monitor the safety of devices which have been placed on the market and/or put into service in compliance with chapter seven of the Law on Medical Devices, and will assess clinical data in compliance with chapter three of the Law on Medical Devices, and implement appropriate means to apply any necessary corrective action taking account of the nature of the risks in relation to the product; the manufacturer shall notify the Bulgarian Drug Agency immediately upon receiving an alert signal related to the following incidents / potential incidents:

aa) any malfunction, failure or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the the instructions for use which might lead to, or might have led to, the death of a patient or user, or to a serious deterioration in his or their state of health;

bb) any technical or medical reason connected with the characteristics or the performance of a device for the reasons referred to in subparagraph (aa) leading to systematic recall of devices of the same type.

3.2. Application of the quality system must ensure that the products conform to the type described in the EC type-examination certificate.

All the elements, requirements and provisions adopted by the manufacturer for his quality system must be documented in a systematic and orderly manner in the form of written policy statements and instructions. This quality system documentation

must permit contain detailed information on the quality programmes, plans, manuals and records, as well as adequate description of:

a) the manufacturer's quality objectives;
b) the organizational structure:

aa) the responsibilities and powers of the managerial staff where manufacture of the devices is concerned;

bb) the methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of the design, including the control of the devices which fail to conform;

cc) (New SF issue 106 of 2008, effective as of 21 March 2010) the methods of monitoring the efficient operation of the quality system and in particular the type and degree of control applied by subcontractors when the manufacture and/or final inspection and investigation of the devices, or their elements, are carried out by subcontractors.

c) the inspection and quality assurance techniques at the manufacturing stage and in particular:

aa) the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents;
bb) the product identification procedures, specifications and other relevant documents at every stage of manufacture;

d) the appropriate tests and investigations to be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it must be possible adequately to trace back the calibration of the test equipment

3.3 The notified body must audit the quality system to determine whether it meets the requirements referred to in paragraph 3.2. It must presume that quality systems which implement the relevant harmonized standards conform to these requirements.

The assessment team must include at least one member with past experience of assessments of the technology concerned. The assessment procedure must include an inspection on the manufacturer's premises and, in some cases, on the premises of the manufacturer's suppliers and/or subcontractors.

The decision of the notified body must contain the conclusions of the inspection and a reasoned assessment. The decision must be notified to the manufacturer.

3.4. The manufacturer must inform the notified body of any plan for substantial changes to the quality system. The notified body must assess the changes proposed and verify whether they meet the requirements referred to in paragraph 3.2. The notified body informs the manufacturer of its decision and delivers to him the conclusion of the inspection and a reasoned assessment.

4. Surveillance

4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality system.

4.2. The manufacturer must allow the notified body access for inspection purposes to the inspection, investigation and storage locations and supply it with all relevant information:

a) the documentation on the quality system;
b) the data stipulated in the part of the quality system relating to manufacture, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.;
c) (New SG issue 106 of 2008, effective as of 21 March 2010) the technical documentation

4.3. The notified body must periodically carry out appropriate inspections and assessments to make sure that the manufacturer applies the approved quality system and supply the manufacturer with an assessment report.

4.4. The notified body may pay unannounced visits to the manufacturer and, where necessary, carry out or ask for tests in order to check that the quality system is working properly. It must provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.

5. (Supplemented SG issue 106 of 2008, effective as of 21 March 2010) The manufacturer must keep for a period ending at least five years, or in the case of implantable devices, at least fifteen years after the last product has been manufactured, the following documentation and make it available, upon request, to the national authorities referred to in Article 86, paragraph 2 of the Law on Medical Devices:

   a) declaration of conformity;
   b) the documentation referred to in paragraph 3.1c;
   c) the documentation referred to in paragraph 3.1g;
   d) the changes referred to in paragraph 3.4;
   e) the decisions and reports referred to in paragraphs 4.3 and 4.4;
   f) where appropriate, the EC type-examination certificate referred to in Annex II

6. (Amended SG issue 106 of 2008, effective as of 21 March 2010) In line with Article 60, this 'Production quality assurance' procedure may apply to products in Class IIa, provided that the following requirements are complied with:

6.1. In derogation from the provisions in paragraphs 2, 3.1 and 3.2, by virtue of the declaration of conformity the manufacturer ensures and declares that the products in Class IIa are manufactured in conformity with the technical documentation referred to in paragraph 3 of Annex VI and meet the requirements of this ordinance which apply to them.

6.2. For devices Class IIa, the notified body is required to evaluate as part of the assessment under paragraph 3.3. the technical documentation referred to in paragraph 3 of Annex VI, at least one representative sample of each device subcategory to assess its conformity to the provisions of this ordinance.

6.3. Regarding the choice of representative sample(s), the notified body will consider the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended use and the results of previous relevant assessments (such as physical, chemical and biological properties) in compliance with the requirements of this ordinance.

The notified body must document the collected information, providing a reasoned statement of its choice of sample(s), and upon request must provided it to the State Agency for Metrology and Technical Surveillance.

6.4. Assessment of additional samples is carried out by the notified body as part of the surveillance procedure under paragraph 4.3.

7. Upon completing the manufacture of each batch of devices referred to in Article 2, paragraph 1 (5), the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by the Bulgarian Drug Agency or a laboratory designated for that purpose by a Member State. This product is an integral part of the device and is liable to act upon the body with action ancillary to that of the device.

Annex V to Article 60, paragraph 1 (3), Article 61, paragraph 2b and Article 63

(Amended SG issue 106 of 2008, effective as of 21 March 2010)

'Product quality assurance'

1. The manufacturer must ensure application of the quality system approved for the final inspection and investigation of the product, as specified in paragraph 3, and subject to the surveillance referred to in paragraph 4.

   In addition, for products placed on the market in sterile condition, and only for those aspects of the manufacturing process designed to secure and maintain sterility, the manufacturer must apply the provisions of paragraphs 3 and 4 of Annex IV.

2. (Amended SG issue 106 of 2008, effective as of 21 March 2010) 'Product quality assurance' is the procedure whereby the manufacturer who satisfies the obligations of paragraph 2 ensures and declares that the product is in conformity with the type as described in the EC-type-examination certificate and meet the requirements of this ordinance which apply to them. The manufacturer must affix the CE marking to each product and draw up a written declaration of conformity. The declaration of conformity covers one or more devices identified by means of product name, product code or other unambiguous reference. The declaration of conformity must be kept by the manufacturer.

3. Quality system.

3.1. The manufacturer shall lodge an application for assessment of his quality system with a notified body of his choice, which includes:

a) the name and address of the manufacturer;
b) all the relevant information on the product or product category covered by the procedure;
c) a written declaration that no application has been lodged with any other notified body for a quality system covering the same products;
d) the documentation on the quality system;
e) an undertaking to fulfil the obligations imposed by the approved quality system;

f) an undertaking to maintain the practicability and effectiveness of the approved quality system;

g) where appropriate, the technical documentation on the types approved and a copy of the EC type-examination certificate;

h) (Amended SG issue 106 of 2008, effective as of 21 March 2010) An undertaking by the manufacturer to institute and keep up to date a systematic procedure to monitor the safety of devices which have been placed on the market and/or put into service in compliance with chapter seven of the Law on Medical Devices, and will assess clinical data in compliance with chapter three of the Law on Medical Devices, and implement appropriate means to apply any necessary corrective action taking account of the nature of the risks in relation to the product; the manufacturer shall notify the Bulgarian Drug Agency immediately upon receiving an alert signal related to the following incidents / potential incidents:

aa) any malfunction, failure or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to, or might have led to, the death of a patient or user, or to a serious deterioration in his or their state of health;

bb) any technical or medical reason connected with the characteristics or the performance of a device for the reasons referred to in subparagraph (aa) leading to systematic recall of devices of the same type.

3.2. Under the quality system, each product or a representative sample of each batch is examined and appropriate tests as set out in the relevant standards and/or monographs under Article 8, or equivalent tests, are be carried out in order to ensure that the products conform to the type described in the EC type-examination certificate and the relevant requirements of this ordinance. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written measures, procedures and instructions. This quality system documentation must permit uniform interpretation of the quality

programmes, quality plans, quality manuals and records, as well as an adequate description of:

a) the quality objectives of the manufacturer and the organizational structure, responsibilities and powers of the managerial staff with regard to product quality;
b) the examinations and tests which will be carried out after manufacture; it must be possible to trace back the calibration during the investigations;
c) the methods of monitoring the effective operation of the quality system;
d) the quality records, such as reports concerning inspections, tests, calibration and the qualifications of the staff concerned, etc.

The aforementioned checks do not apply to those aspects of the manufacturing process designed to secure sterility.

e) (New SG issue 106 of 2008, effective as of 21 March 2010) the methods of monitoring the efficient operation of the quality system and in particular the type and degree of control applied by subcontractors when the manufacture and/or final inspection and investigation of the devices, or their elements, are carried out by subcontractors.

3.3. The notified body audits the quality system to determine whether it meets the requirements referred to in paragraph 3.2. It must presume that quality systems which implement the relevant harmonized standards conform to these requirements.

The assessment team must include at least one member with past experience of assessments of the technology concerned. The assessment procedure must include an inspection on the manufacturer's premises and, in some cases, on the premises of the manufacturer's suppliers and/or subcontractors.

The decision of the notified body must contain the conclusions of the inspection and a reasoned assessment. The decision must be notified to the manufacturer.

3.4. The manufacturer must inform the notified body of any plan for substantial changes to the quality system. The notified body must assess the changes proposed and verify whether they meet the requirements referred to in paragraph 3.2. The notified body informs the manufacturer of its decision and delivers to him the conclusion of the inspection and a reasoned assessment.

4. Surveillance

4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality system.

4.2. The manufacturer must allow the notified body access for inspection purposes to the inspection, investigation and storage locations and supply it with all relevant information, in particular:

a) the documentation on the quality system;
b) the technical documentation;
c) the quality records, such as inspection reports, test data, calibration data, qualification reports of the staff concerned, etc.

4.3. The notified body must periodically carry out appropriate inspections and assessments to make sure that the manufacturer applies the quality system and must supply the manufacturer with an assessment report.

4.4. In addition, the notified body may pay unannounced visits to the manufacturer and, where necessary, carry out or ask for tests in order to check that the quality system is working properly and that the production conforms to the requirements of this ordinance which apply to it. To this end, an adequate sample of the final products, taken on site by the notified body, must be examined and the appropriate tests defined in the relevant standards and/or monographs referred to in Article 8 or equivalent tests must be carried out. Where one or more of the samples fails to conform, the notified

body must take the appropriate measures. It must provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.

9. (Supplemented SG issue 106 of 2008, effective as of 21 March 2010) The manufacturer must keep for a period ending at least five years, or in the case of implantable devices, at least fifteen years after the last product has been manufactured, the following documentation and make it available, upon request, to the national authorities referred to in Article 86, paragraph 2 of the Law on Medical Devices:

a) declaration of conformity;
b) the technical documentation referred to in paragraph 3.1g;
c) the changes referred to in paragraph 3.4;
d) the decisions and reports of the notified body referred to in paragraph 3.4 and in paragraphs 4.3 and 4.4;
e) where appropriate, the EC type-examination certificate referred to in Annex II.

6. (Amended SG issue 106 of 2008, effective as of 21 March 2010) In line with Article 60, the 'Product quality assurance' may apply to products in Class IIa, provided that the following requirements are complied with:

6.1 In derogation from paragraphs 2, 3.1 and 3.2, by virtue of the declaration of conformity the manufacturer ensures and declares that the products in Class IIa are manufactured in conformity with the technical documentation referred to in paragraph 3 of Annex VI and meet the requirements of this ordinance which apply to them.

6.2 For devices Class IIa, the notified body is required to evaluate as part of the assessment under paragraph 3 of Annex VI at least one representative sample of each device subcategory to assess its conformity to the provisions of this ordinance.

6.3 Regarding the choice of representative sample(s), the notified body will consider the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended use and the results of previous relevant assessments (such as physical, chemical and biological properties) in compliance with the requirements of this ordinance.

The notified body must document the collected information, providing a reasoned statement of its choice of sample(s), and upon request must provided it to the State Agency for Metrology and Technical Surveillance.

6.4 Assessment of additional samples is carried out by the notified body as part of the surveillance procedure under paragraph 4.3.

Annex VI to Article 60, paragraph 1, article 62 and 64

(Amended SG issue 106 of 2008, effective as of 21 March 2010)

'EC Declaration of conformity'

1. The 'EC declaration of conformity' is a procedure whereby the manufacturer or his authorized representative who fulfils the obligations imposed by paragraph 2 and, in the case of products placed on the market in a sterile condition and devices with a measuring function, the obligations imposed by paragraph 5, ensures and declares that the products concerned meet the provisions of this ordinance which apply to them.

2. (Supplemented SG issue 106 of 2008, effective as of 21 March 2010) The manufacturer must prepare the technical documentation described in paragraph 3. The manufacturer or his authorized representative keep this documentation and must make it available, including the declaration of conformity, to the national authorities referred to in Article 82, paragraph 2 of the Law on Medical Devices, for inspection purposes for a period ending at least five years, and in the

case of implantable devices, for a period ending at least fifteen years after the last product has been manufactured.

3. (Amended SG issue 106 of 2008, effective as of 21 March 2010) The technical documentation must allow assessment of the conformity of the product with the requirements of this ordinance. It must include in particular:

a) a general description of the product, including any variants planned and its intended purpose(s);
b) design drawings, methods of manufacture envisaged and diagrams of components, sub-assemblies, circuits, etc.;
c) the descriptions and explanations necessary to understand the abovementioned drawings and diagrams and the operations of the product;
d) the results of the risk analysis and a list of the standards and/or monographs referred to in Article 8, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of this ordinance, if the standards and/or monographs referred to in Article 8 have not been applied in full;
e) in the case of products placed on the market in a sterile condition, description of the methods used;
f) the results of the design calculations and of the inspections carried out, etc.;
g) if the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device(s);
h) the solutions adopted by the manufacturer under Article 11;
i) all preclinical data;
j) all clinical data related to the devices in accordance with chapter three of the Law on Medical Devices;
k) the label and instructions for use

4. (Amended SG issue 106 of 2008, effective as of 21 March 2010) The manufacturer must institute and keep up to date a systematic procedure to monitor the safety of devices which have been placed on the market and/or put into service and apply any necessary corrective action taking account of the

nature of the risks in relation to the product. The manufacturer shall notify the Bulgarian Drug Agency immediately upon receiving an alert signal related to the following incidents / potential incidents:

a) any malfunction, failure or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to, or might have led to, the death of a patient or user, or to a serious deterioration in his or their state of health;

c) any technical or medical reason connected with the characteristics or the performance of a device for the reasons referred to in subparagraph (a) leading to systematic recall of devices of the same type.

5. (Amended SG issue 106 of 2008, effective as of 21 March 2010) With products placed on the market in sterile condition and Class I devices with a measuring function, the manufacturer must observe not only the provisions laid down in this Annex and one of the procedures referred to in Annexes I, III, IV or V. Application of the abovementioned Annexes and the intervention by the notified body is limited to:

a) in the case of products placed on the market in sterile condition, only the aspects of manufacture concerned with securing and maintaining sterile conditions;

b) in the case of devices with a measuring function, only the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

6. In line with Article 60, the 'EC declaration of conformity' procedure may apply to products in Class IIa, provided that the following requirement is complied with:

Where this 'EC declaration of conformity' procedure is applied in conjunction with the procedures referred to in Annexes № III, IV and V, the declaration of conformity is certified by a single declaration.

As regards the declaration based on this Annex, the manufacturer must ensure and declare that the product design meets the provisions of this ordinance which apply to it.

Annex VII to Article 59, paragraph 2

Risk analysis and risk management

Risk analysis and risk management

1. Risk analysis and risk management

1.1. Justification for the use of animal tissues or derivatives

The manufacturer must justify, on the basis of his overall risk analysis and risk management strategy for a specific medical device, the decision to use animal tissues or derivatives, referred to in Article 2, paragraph 2 (specifying animal species and tissues) taking into account the expected clinical benefit, potential residual risk and suitable alternatives.

1.2. Assessment procedure

In order to ensure a high level of protection for patients or users, the manufacturer of devices utilising animal tissues or derivatives must implement an appropriate and well documented risk analysis and risk management strategy, to address all relevant relating aspects to transmissible spongiform encephalopathy. He must identify the hazards associated with those tissues or derivatives, establish documentation on measures taken to minimise the risk of transmission and demonstrate the acceptability of the residual risk associated with the devices referred to in Article 2, paragraph 1 (9), taking into account the intended use and the benefit of the device.

The safety of a device, in terms of its potential for passing on a transmissible agent, is dependent on all the factors described in points 1.2.1 to 1.2.7, which must be analysed, evaluated and managed. These measures in combination determine the device safety.

There are two key steps that must be considered:

- selecting starting materials (tissues or derivatives) considered appropriate regarding their potential contamination with transmissible agents (see 1.2.1, 1.2.2 and 1.2.3) taking into account further processing;
- applying a production process to remove or inactivate transmissible agents on controlled sourced tissues or derivatives (see 1.2.4)

Furthermore, the characteristics of the device and its intended use must be taken into account (see 1.2.5, 1.2.6 and 1.2.7).

In performing the risk analysis and risk management strategy, due consideration must be given to opinions adopted by the relevant scientific committees, and, where appropriate, to the opinions of the Committee for Medicinal Products at the European Medicines Agency.

1.2.1 Animals as a source of material

The transmissible spongiform encephalopathy (TSE) risk is related to the source species, strains and nature of the starting tissue. As the accumulation of TSE infectivity occurs over an incubation period of several years, sourcing from young healthy animals is considered to be a factor reducing the risk. Risk animals such as fallen stock, emergency slaughtered and TSE suspected animals must be excluded.

1.2.2 Geographical sourcing

Depending on the classification of countries according to the BSE (bovine spongiform encephalopathy) status in Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and

eradication of certain transmissible spongiform encephalopathies (OJ, L 147 of 31 May 2001, pp. 1-40), the Geographical BSE risk (GBR) is used when assessing the risk of the source country. The geographical BSE risk is a qualitative indicator of the likelihood of the presence of one or more cattle being infected with transmissible spongiform encephalopathy, pre-clinically as well as clinically, at a given point in time, in a country. Where presence is confirmed, the GBR gives an indication of the level of infection as specified in the table below.

GBR level	Presence of one or more cattle clinically or pre-clinically infected with the BSE agent in a geographical region/country
I	Highly unlikely
II	Unlikely but not excluded
III	Likely but not confirmed or confirmed, at a lower level
IV	Confirmed, at a higher level

Certain factors influence the geographical risk of BSE infection associated with the use of raw tissues or derivatives from individual countries. These factors are defined in Article 2.3.13.2, point 1, of the International Animal Health Code of the World Organisation for Animal Health / Office International des Épizooties (OIE).

The Scientific Steering Committee has made an assessment of Geographical BSE Risk (GBR) of several third countries and Member States, and will continue to do so for all the countries, which applied for BSE status categorisation, taking the main OIE factors into account.

1.2.3. Nature of starting tissue

The manufacturer must take into account the classification of the hazards relating to different type of starting tissue. Sourcing of animal tissue must be subject to control and individual inspection by a veterinarian and the animal carcass must be certified as fit for human consumption.

The manufacturer must ensure that no risk of cross-contamination occurs at the time of slaughtering.

The manufacturer must not source animal tissue or derivatives classified as potentially high TSE infectivity, unless sourcing of these materials is necessary in exceptional circumstances, taking into account the important benefit for the patient and the absence of an alternative starting tissue.

In addition, the provisions in Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption must be observed.

1.2.3.1 Sheep and goats

A classification of infectivity in tissues for sheep and goats has been established based on actual knowledge on the basis of the titres of transmissible agents in tissues and body fluids from naturally infected sheep and goats with clinical scrapie. A table was presented in the Scientific Steering Committee (SSC) opinion of 22-23 July 1999 on 'The policy of breeding and genotyping of sheep', and further updated in the opinion of the SSC adopted on 10-11 January 2002 on TSE infectivity distributed in ruminant tissues state of knowledge December 2001.

This classification may be reviewed in the light of new scientific evidence (for example using relevant opinions from the Scientific Committees, the Committee for Proprietary Medicinal Products and Commission measures regulating the use of material presenting risks as regards TSE. A review of the references to relevant documents/opinions will be published in the Official Journal of the European Union and will be listed after a Commission Decision has been taken.

1.2.3.2. Cattle

The tissues defined as specified risk material (SRM) laid down in Annex V of Regulation (EC) No 999/2001 shall be considered as potentially high TSE infective.

1.2.4. Inactivation or removal of transmissible agents

1.2.4.1. For devices which cannot withstand an inactivation/elimination process without undergoing unacceptable degradation, the manufacturer must rely principally on the control of sourcing.

1.2.4.2. When the manufacturer makes claims for the ability of manufacturing processes to remove or inactivate transmissible agents, he must substantiate them with appropriate documentation.

Relevant information from an appropriate scientific literature search and analysis can be used to support inactivation/elimination factors, where the specific processes referred to in the literature are comparable to those used for the device. This search and analysis must also cover the available scientific opinions that may have been adopted by a EU Scientific Committee. These opinions shall serve as a reference, in cases where there are conflicting opinions.

When the literature search failed to substantiate the claims, the manufacturer must set up a specific inactivation and/or elimination study on a scientific basis and the following elements need to be considered:

- identification of the hazard associated with the tissue;
- identification of the relevant model agents;
- justification of the choice of the particular combinations of model agents;
- identification of stage chosen to eliminate and/or inactivate the transmissible agents;
- calculation of the reduction factors

The final report must identify the manufacturing parameters and limits that are critical to the effectiveness of the inactivation or elimination process.

Appropriate documented procedures must be applied to ensure that the validated processing parameters are applied during production processes.

1.2.5. Quantities of animal starting tissues or derivatives required to produce one unit of the medical device

The manufacturer must evaluate the quantity of raw tissues or derivatives of animal origin required to produce a single unit of the medical device. Where a purification process is involved, the manufacturer must assess whether it may have the potential to concentrate levels of transmissible agents present in the animal starting tissues or derivatives.

1.2.6. Tissues or derivatives of animal origin coming into contact with the patients and users.

The manufacturer must consider:

a) the quantity of animal tissues or derivatives;
b) the contact area: its surface, type (e.g. skin, mucous tissue, brain) and condition (e.g. healthy or damaged);
c) the type of the tissues or derivatives coming into contact with the patients and/or users;
d) how long the device is intended to remain in contact with the body (including bioresorption effect)

The manufacturer must take into account the number of medical devices that could be used in a given procedure.

1.2.7. Route of administration

The manufacturer must take into account the route of administration recommended in the product information, from the highest risk down to the lowest.

1.3. Review of the assessment

The manufacturer must establish and maintain a systematic procedure to review information gained about his medical device or similar devices in the post-production phase. The information must be evaluated for possible relevance to safety, especially:

a) if previously unrecognised hazards are detected;
b) if the estimated risk arising from a hazard is no longer acceptable;
c) if the original assessment is otherwise invalidated

If any of the above cases, the results of the evaluation shall be taken into account in the risk management process.
In the light of this new information, a review of the appropriate risk management measures for the device must be considered (including review of the reason for choosing an animal tissue or derivative). If there is a potential that the residual risk or its acceptability has changed, the impact on previously implemented risk control measures must be re-evaluated and justified.

The results of this evaluation must be documented.

2. Evaluation of class III medical devices by notified bodies

For devices falling into Class III, manufacturers must provide to the notified bodies all relevant information to allow evaluation of their current risk analysis and risk management strategy. Any new information on TSE risk, collected by the manufacturer and relevant for his devices must be sent to the notified body.

Any change in relation to processes of sourcing, collection, handling and inactivation/elimination and that could modify the result of the manufacturer's risk management documentation must be transmitted to the notified body for the purpose of an additional approval prior to its implementation.

Annex VIII to Article 9

(Amended SG issue 106 of 2008, effective as of 21 March 2010)

Classification rules

1. Definitions for the classification rules:

1.1. Duration:

a) (Amended SG issue 106 of 2008, effective as of 21 March 2010) Transient – normally intended for continuous use for less than 60 minutes;

b) (Amended SG issue 106 of 2008, effective as of 21 March 2010) Short-term – normally intended for continuous use for less than 30 days;

c) (Amended SG issue 106 of 2008, effective as of 21 March 2010) Long-term – normally intended for continuous use for more than 30 days

1.2. Invasive devices:

a) a device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body

Body orifice is any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening (ileostomy, colostomy, tracheotomy)

b) a surgically invasive device is any device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation. The devices other than those referred to in subparagraph 'b' and which produce penetration other than through an established body orifice, shall be treated as surgically invasive devices.

c) an implantable device is any device which is intended to be totally introduced into the human body or to replace an epithelial surface or the surface of the eye, by surgical intervention which is intended to remain in place after the procedure.

Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device.

1.3. Reusable surgical instruments are instruments intended for surgical use by cutting, drilling, sawing, clamping, retracting or similar procedures, without connection to any active medical device and which can be reused after appropriate procedures have been carried out.

1.4. (Supplemented SG issue 106 of 2008, effective as of 21 March 2010) Active medical device is any medical device operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy.

Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to he active medical devices.

The independent software is considered an active medical device.

1.5. Active therapeutic device is any active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap.

1.6. Active device for diagnosis is any active medical device, whether used alone or in combination with other medical devices, to supply information for diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.

1.7. (Amended SG issue 106 of 2008, effective as of 21 March 2010) Central circulatory system

For the purposes of this ordinance ‘central circulatory system’ means the following vessels: arteriae pulmonales, arteriae coronariae, aorta ascendens, arcus aorta, aorta descendens to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior, vena cava inferior

1.8. Central nervous system

For the purposes of this ordinance, ‘central nervous system’ means brain, meninges and spinal cord.

2. Implementing rules

2.1. Application of the classification rules shall be governed by the intended purpose of the devices.

2.2. If the device is intended to be used in combination with another device the classification rules shall apply separately to each of the devices. Accessories are classified in their own right separately from the device with which they are used.

2.3. Software, which drives a device or influences the use of a device, falls automatically in the same class.

2.4. If the device is not intended to be used solely or principally in a specific part of the body, it must be considered and classified on the basis of the most critical specified use.

2.5. If several rules apply to the same device, based on the performance specified for the device by the manufacturer, the strictest rules resulting in the higher classification shall apply.

2.6. (New SG issue 106 of 2008, effective as of 21 March 2010) In calculating the duration referred to in paragraph 1.1, 'continuous use' means 'an uninterrupted actual use of the device for the intended purpose'. However, where usage of a device is discontinued in order for the device to be replaced immediately by the same or an identical device this shall be considered an extension of the continuous use of the device.

3. Classification

3.1. Non-invasive devices

3.1.1. Rule 1. All non-invasive devices are in Class I, unless one of the rules set out hereinafter applies.

3.1.2. Rule 2. All non-invasive devices intended for channelling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion or introduction into the body are in Class IIa:

a) if they may be connected to an active medical device in Class IIa or a higher class;
b) if they are intended for storing or channelling blood or other body liquids, or for storing organs, body tissues or cells

In all cases other than those specified in subparagraphs 'a' and 'b' above, the non-invasive devices intended for storing or channelling blood, body fluid or tissues, or other liquids or gases, for the purpose of eventual infusion, administration or introduction into the body are in Class I.

3.1.3. Rule 3. All non-invasive devices intended for infusion of blood, body fluids or other liquids in the body for the purposes of modifying their biological or chemical composition, are in Class IIb, unless the treatment consists of filtration, centrifugation or exchanges of gas, heat, in which case they are in Class IIa.

3.1.4. Rule 4. All non-invasive devices which come into contact with injured skin:

a) are in Class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates;
b) are in Class IIb if they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent (non-surgical recovery of the skin wound);
c) are in Class IIa in all cases other than those specified in subparagraphs 'a' and 'b', including devices principally intended to manage the micro-environment of a wound

3.2. Invasive devices

3.2.1. (Supplemented SG issue 106 of 2008, effective as of 21 March 2010) Rule 5. All invasive devices with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device or which are intended for connection to an active medical device in Class I:

a) are in Class I, if they are intended for transient use;
b) are in Class IIa, if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in Class I;
c) are in Class IIb, if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class IIa;

All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to an active medical device in Class IIa or a higher class, are in Class IIa.

3.2.2. Rule 6. All surgically invasive devices intended for transient use are in Class IIa unless they are:

a) (Amended SG issue 106 of 2008, effective as of 21 March 2010) intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III;

b) reusable surgical instruments, in which case they are in Class I;

c) intended to supply energy in the form of ionising radiation in which case they are in Class IIb;

d) intended to have a biological effect or to be wholly or mainly absorbed in which case they are in Class IIb;

e) intended to administer medicines by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are in Class IIb;

f) (New SG issue 106 of 2008, effective as of 21 March 2010) intended specifically for use in direct contact with the central nervous system, in which case they are in Class III

3.2.3. Rule 7. All surgically invasive devices intended for short-term use are in Class IIa unless they are intended:

a) (Supplemented SG issue 106 of 2008, effective as of 21 March 2010) either specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III;

b) (Supplemented SG issue 106 of 2008, effective as of 21 March 2010) or specifically for use in direct contact with the central nervous system, in which case they are in Class III;

c) or to supply energy in the form of ionizing radiation in which case they are in Class IIb;

d) or to have a biological effect or to be wholly or mainly absorbed in which case they are in Class III;

e) or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class IIb

3.2.4. Rule 8. All implantable devices and long-term surgically invasive devices are in Class IIb unless they are intended:

a) to be placed in the teeth, in which case they are in Class IIa;

b) to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class III;

c) to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class III;

d) or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class III

3.2.5. As exception to Rule 8, all breast implants are in Class III.

3.2.6. As exception to Rule 8, the hip, knee, and shoulder joint replacements are in Class III as of 1 September 2007.

3.3. Additional rules applicable to active devices.

3.3.1. Rule 9. All active therapeutic devices intended to administer or exchange energy are in Class IIa unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are in Class IIb.

All active devices intended to control or monitor the performance of active therapeutic devices in Class IIb, or intended directly to influence the performance of such devices are in Class IIb.

3.3.2. Rule 10. Active devices intended for diagnosis are in Class IIa:

a) if they are intended to supply energy which will be absorbed by the human body, except for devices used to illuminate the patient's body, in the visible spectrum;

b) if they are intended to image distribution of radiopharmaceuticals in the body;

c) if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of CNS in which case they are in Class IIb

Active devices intended to emit ionizing radiation and intended for diagnostic and therapeutic interventional radiology including devices which control or monitor such devices, or which directly influence their performance, are in Class IIb.

3.3.3. Rule 11. All active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body are in Class IIa, unless this is done in a manner that is potentially hazardous, taking account of the

nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are in Class IIb;

3.3.4. Rule 12. All other active devices are in Class I.

3.4. Special rules

3.4.1. (Amended SG issue 106 of 2008, effective as of 21 March 2010) Rule 13. All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in the Law on the Medicinal Products in Human Medicine and which is liable to act on the human body with action ancillary to that of the devices, are in Class III.

All devices incorporating, as an integral part, a human blood or human plasma derivative are in Class III.

3.4.2. Rule 14. All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class IIb, unless they are implantable or long term invasive devices, in which case they are in Class III.

3.4.3. (Supplemented AG issue 106 of 2008, effective as of 21 March 2010) Rule 15. All devices intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are in Class IIb.

All devices intended specifically to be used for disinfecting medical devices are in Class IIa, unless they are specifically to be used for disinfecting invasive devices in which case they are in Class IIb.

This rule does not apply to products that are intended to clean medical devices other than contact lenses by means of physical action.

3.4.4. (Amended SG issue 106 of 2008, effective as of 21 March 2010) Rule 16. Devices specifically intended for recording of X-ray diagnostic images are in Class IIa.

3.4.5. Rule 17. All devices manufactured utilizing animal tissues or derivatives rendered non-viable are Class III except where such devices are intended to come into contact with intact skin only.

3.5. Rule 18. Blood bags are in Class IIb.