POLSKÝ ZÁKON O ZDRAVOTNICKÝCH PROSTŘEDCÍCH – ANGLICKÝ PŘEKLAD

ACT OF 20 APRIL 2004 ON MEDICAL DEVICES

Chapter 1 General provisions

Article 1.

1. This Act specifies:
1)placing on the market and putting into service of medical devices
2) clinical assessment of medical devices
3) conditions of use of medical devices
4) surveillance over the manufacturing, placing on the market and putting into service of medical devices
5) surveillance over medical devices placed on the market and put into service
6) reporting medical incidents involving medical devices and procedure following such reporting
7) the form of keeping the Register of medical devices and entities responsible for their placing on the market and putting into service
8) the rules and procedure for authorising as well as notifying, supervising, restricting and withdrawing the authorisation of bodies notified in the field of medical devices and the authorities competent in these cases
9) classification and qualification of medical devices
10) assessment of conformity of medical devices
11) essential requirements for medical devices. 2. Any issues which are not specifically regulated in this Act shall be governed by the provisions of the Code of Administrative Procedure.

Article 2.

1. This Act shall not apply to:
1)medicinal products
2) biocides
3) cosmetics
4) means of individual protection
5) implants of tissues and cells of human origin and medical devices for various purposes containing or derived from such tissues or cells, except for medical devices for various purposes containing blood derivatives
6) implants of tissues and cells of animal origin and medical devices for various purposes containing such tissues or cells, unless tissues or cells considered non-viable or non-viable products derived from such tissues or cells are used in a medical device for various purposes
7) in vitro diagnostic medical devices manufactured and used only within the same health care centre or used on premises in the immediate vicinity of this health care centre without having been transferred to another health care centre
8) in vitro diagnostic medical devices intended to be used solely in scientific research conducted for purposes other than medical ones
9) reference materials with international certificates and materials used for the purposes of external quality assessment project.

Article 3.

1. Whenever in this Act there is a reference to:

1)active implantable medical device – it shall mean any medical device relying for its proper functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity, which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and to remain after the procedure

2) authorised representative – it shall mean any natural person, organisational unit having no legal personality, or legal person established within the territory of the European Union Member State or the European Free Trade Agreement (EFT a) Member State, being a party to the European Economic Area Agreement, that is explicitly designated by the manufacturer to act in its name and may be addressed, instead of the manufacturer, by authorities and bodies of the European Union Member States or the European Free Trade Agreement (EFT a) Member States, being parties to the European Economic Area Agreement, in cases concerning the duties of manufacturers as specified in this Act

3) investigator – it shall mean a person with suitable professional qualifications authorising him or her to do clinical investigations, taking into consideration scientific background and experience with patients which is necessary for such investigation

if the investigation is conducted by a team of persons, the responsible leader shall be a doctor or a dentist surgeon

4) serious undesirable side effect – it shall mean any undesirable side effect causing demise, need of hospitalisation or its extension due to risk of demise or deterioration of the health condition, or the need of medical intervention, permanent or significant detriment to health, demise of foetus, congenial abnormality, perinatal injury or carcinogenic lesion, or any event which the investigator considers significant from medical point of view

5) distributor – it shall mean any natural person, organisational unit having no legal personality, or legal person, marketing a medical device originating from the European Union Member State or the European Free Trade Agreement (EFT a) Member State, being a party to the European Economic Area Agreement, in order to be used or distributed within the territory of the Republic of Poland, such distributor not being the user of such medical device

6) importer – it shall mean any natural person, organisational unit having no legal personality, or legal person established within the territory of the European Union Member State or the European Free Trade Agreement (EFT a) Member State, being a party to the European Economic Area Agreement, marketing a medical device originating from outside the European Union Member State or the European Free Trade Agreement (EFT a) Member State, being a party to the European Economic Area Agreement, in order to be used or distributed within the territory of the European Union Member State or the European Free Trade Agreement (EFT a) Member State, being a party to the European Economic Area Agreement

7) medical incident involving a medical device – it shall mean:

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

b) systematic recall of medical devices of the same type by the manufacturer for technical or medical reason, in relation to the characteristics or performance of a medical device, in cases referred to in letter a)

8) invasive medical device – it shall mean a medical device for various purposes which, in whole or in part, penetrates inside the human body, either through a natural orifice or through the surface of the body

9) undesirable side effect – it shall mean any undesirable clinical phenomenon occurring with a participant of investigation, whether considered related to the medical device or not, and irregular results of laboratory testing

10) entity responsible for placing a medical device on the market – it shall mean any natural person, organisational unit having no legal personality, or legal person established within the territory of the European Union Member State or the European Free Trade Agreement (EFT a) Member State, being a party to the European Economic Area Agreement, responsible for placing a medical device on the market, who is explicitly designed by the manufacturer established outside the territory of the European Union Member State or the European Free Trade Agreement (EFT a) Member State, being a party to the European Economic Area Agreement, if such manufacturer did not designate his authorised representative

11) intended purpose – it shall mean the use for which the medical device is intended according to the data supplied by the manufacturer on the labelling, in the instructions for use or in promotional materials

12) sponsor- it shall mean a manufacturer or its authorised representative with responsibility for undertaking, conducting, and financing the clinical investigations

13) placing on the market – it shall mean the first making available in return for payment or free of charge of a medical device other than a medical device intended for clinical investigations or an in vitro diagnostic medical device for performance evaluation with a view to use or distribution in the territory of the European Union Member State or the European Free Trade Agreement (EFT a) Member State, being a party to the European Economic Area Agreement, regardless of whether it is new or fully refurbished

14) putting into service – it shall mean the stage at which a medical device has been made available to the final user as being ready for use in the territory of the European Union Member State or the European Free Trade Agreement (EFT a) Member State, being a party to the European Economic Area Agreement, for the first time for its intended purpose

15) accessories to medical device for various purposes – it shall mean articles which, whilst not being medical devices, are intended specifically to be used together with a medical device to enable that device to be used in accordance with its purpose as intended by the manufacturer

16) accessories to in vitro diagnostic medical device – it shall mean articles which, whilst not being in medical devices, are intended specifically to be used together with a medical device to enable that device to be used in accordance with its purpose as intended by the manufacturer, except for invasive sampling medical devices or those which are directly applied to the human body for the purpose of obtaining a specimen

17) medical device – it shall mean any tool, instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

a) diagnosis, prevention, monitoring, treatment or alleviation of disease
b) diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap
c) investigation, replacement or modification of the anatomy or of a physiological process
d) control of conception

- and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

18) in vitro diagnostic medical device – it shall mean:

a) any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or primarily for the purpose of providing information: - concerning a physiological or pathological state, or - concerning a congenital abnormality, or - to determine the safety and compatibility between potential donor and recipient, or - to monitor therapeutic measures

b) specimen receptacles, whether vacuum-type or not, specifically intended by their manufacturer for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination

c) products for general laboratory use, if such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination

19) in vitro diagnostic medical device for self-testing – it shall mean any in vitro diagnostic medical device intended by the manufacturer to be able to be used by lay persons in a home environment

20) in vitro diagnostic medical device for performance evaluation – it shall mean any in vitro diagnostic medical device intended to be subject to one or more performance evaluation studies in laboratories for medical analyses or in other appropriate environments outside the manufacturer's premises

21) medical device for clinical investigation – it shall mean any medical device, other than in vitro diagnostic medical device, intended by the manufacturer to be used by the investigator in order to perform the clinical investigation stipulated in this Act

22) custom-made medical device – it shall mean any medical device specifically made according to a written prescription of a doctor or another person with suitable professional qualifications, which gives, under their responsibility, specific design characteristics and intended purpose, and is intended for the sole use of a particular patient, except for mass-produced medical devices which need to be adapted to meet the specific requirements of a doctor or any other user 23) new device – it shall mean an in vitro diagnostic medical device, if there has been no such device continuously available within the territory of the European Union Member State or the European Free Trade Agreement (EFT a) Member State, being a party to the European Economic Area Agreement, during the previous three years for the relevant analyte or other parameter or where the procedure applied is based on analytical technology not continuously used in connection with a given analyte or other parameter within the territory of the European Union Member State or the European Free Trade Agreement (EFT a) Member State, being a party to the European Economic Area Agreement, during the previous three years

24) manufacturer – it shall mean any natural person, organisational unit having no legal personality, or legal person with responsibility for the design, manufacture, packaging, labelling, assembly, processing and full refurbishment of a medical device or assigning to the device its intended purpose before the device is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party

except for entities assembling or adapting medical devices already on the market to their intended purpose for an individual patient. 2. Whenever in this Act there is a reference to a medical device for various purposes, with no further specification, it shall mean a medical device other than an active implantable medical device or an in vitro diagnostic medical device. 3. Whenever in this Act there is a reference to a medical device with no further specification it shall mean a medical device for various purposes, an in vitro diagnostic medical device, an active implantable medical device, as well as accessories to diagnostic medical for various purposes, and accessories to in vitro diagnostic medical devices. Chapter 2 Placing on the market and putting into service of medical devices

Article 4.

1. Medical devices may be placed on the market and put into service only if they comply with the requirements laid down in this Act. 2. Medical devices which are being placed on the market and put into service must be properly delivered, correctly installed and maintained, and used for their purpose as intended by the manufacturer. The device shall not compromise the safety or health of patients, users or third parties. 3. Entities authorised to place on the market and put into service

the medical devices, hereinafter referred to as “authorised entities”, shall be the manufacturer, his authorised representative, importer, distributor, and the entity responsible for placing a medical device on the market. 4. Users shall exercise due care when choosing, installing, starting-up, testing, and maintaining the medical devices, and in particular they shall comply with the instructions for use attached by the manufacturer. 5. Authorised entities marketing the medical devices in the territory of the Republic of Poland shall label the devices in the Polish language and supply to the user the instructions for use and the labels in the Polish language. In relation to the devices intended for use by professionals it is admissible that, upon the user’s consent, the user is supplied with the required information in a language other than Polish. 6. If the medical devices is intended to be use by professionals than ,after user acceptance , the user is supplied with the information required in a language other than Polish.

Article 5.

1. Medical devices may be placed on the market and put into service after CE marking has been affixed on them. 2. The CE marking shall be affixed on the device which has undergone relevant procedures of assessment of conformity with the essential requirements referred to in Chapter 4. 3. The CE marking shall not be affixed on custom-made medical devices, medical device intended for clinical investigations and in vitro diagnostic medical devices for performance evaluation. 4. The minister competent for health shall, by Regulation, determine the specimen CE marking, considering the need to ensure its compliance with relevant European Union regulations on medical devices.

Article 6.

1. The CE marking must appear in a visible, legible and indelible form on the instructions for use, on the commercial packaging and, where practicable and appropriate, on the medical device and its sterility-assuring packaging. 2. If conformity assessment was conducted under the supervision of a body notified in the field of medical devices, hereinafter referred to as “notified body”, the CE marking shall be accompanied by the identification number of such notified body. 3. It is prohibited to affix on the medical device, its packaging or instructions for use any marks or inscriptions which are likely to mislead third parties with regard to the CE marking affixed or the identification number assigned to the notified body.

Article 7.

If a manufacturer, invoking the provisions of this Act, affixes a CE marking on a device which is not a medical device, he shall remove such marking from the device.

Article 8.

1. If different medical devices for various purposes with CE marking are put together to form a set, in accordance with their intended purpose and limitations specified by the manufacturer, in order to be placed on the market as a system or procedure pack, a person performing such a set shall make a statement to confirm that: 1) mutual conformity of particular medical devices as per instructions from manufacturers was verified and the actions specified in such instructions were performed

2) the system or procedure pack was packed and accompanied by suitable instructions for use together with instructions of particular medical devices contained in this system or pack

3) the actions referred to in subparagraphs 1 and 2 were subject to internal control. 2. In case where the conditions referred to in paragraph 1 are not met, in particular where a system or procedure pack contains a medical device bearing no CE marking or where a medical device was incorporated into this system or pack at variance with its intended purpose, such system or pack shall be subject to conformity assessment procedure. 3. If a system or procedure pack or some

other medical device for various purposes bearing a CE marking is intended by the manufacturer for sterilisation before use, its sterilisation before placing on the market requires that: 1) the sterilising entity conducts a conformity assessment procedure, limited to sterilisation-related issues, under supervision of a notified body
2) sterilisation is conducted as per the manufacturer's instructions. 4. The sterilising entity shall make a statement confirming that the sterilisation was conducted in accordance with the manufacturer's instructions. 5. The statements referred to in paragraphs 1 and 4 shall be safe-kept for five years after their issue date. 6. A system or procedure pack, or a medical device bearing a CE marking, intended by the manufacturer for sterilisation before use as referred to in paragraph 3, shall not bear a CE marking.

Article 9.
1. The minister competent for health may, by decision, admit to use, in exceptional cases, without the need to conduct the conformity assessment procedure referred to in Chapter 4, single pieces of medical devices, if their application is necessary to save a patient's life or health, subject to paragraph 3. 2. The basis for admitting to use the device referred to in paragraph 1 is the demand reported by a health care centre or the doctor offering treatment outside the health care centre. 3. Admittance to use as referred to in paragraph 1 shall not apply to a medical device which has been recalled from the market and service due to a failure to meet the requirements concerning safety or performance effectiveness.

Article 10.
1. A medical device which fails to meet the requirements stipulated in the Act may be displayed, in particular during fairs, exhibitions, and demonstrations, provided that it bears a marking clearly indicating that the device cannot be placed on the market or put into service until it has undergone the conformity assessment procedure. 2. In vitro diagnostic medical devices referred to in paragraph 1 cannot be used for testing the specimens obtained from the participants of fairs, exhibitions, and demonstrations.

Article 11.
Medical devices cannot be placed on the market and put into service, if their marking or instructions for use may be misleading as to the characteristics and performance of the devices, in particular where: 1) they specify the properties, functions, and effects that the device does not have
2) they fail to inform about risk connected with the use of the medical device
3) they suggest the intended purpose other than declared during the conformity assessment procedure.

Article 12.
If the manufacturer fixed a validity period for the medical device, this device cannot be placed on the market or put into service after its validity period has expired. Chapter 3 Classification and qualification of medical devices
Article 13.
1. Medical devices for various purposes shall be divided into Class I, IIa, IIb, and III ones, depending on potential risk connected with their use. 2. The minister competent for health shall, by Regulation, determine the mode of classification of medical devices for various purposes, taking into consideration the European Union regulations on medical devices as well as risk of use and intended purpose of a particular medical device.

Article 14.

In vitro diagnosis medical devices shall be qualified, depending on the potential risk connected with their use, as belonging to devices: put on list A, put on list B, in vitro diagnosis medical devices for self-testing, and other in vitro diagnosis medical devices.

Article 15.
Classification and qualification of a medical device shall be performed by its manufacturer. Discrepancies concerning classification and qualification of a medical device between the manufacturer and the notified body authorised by the minister competent for health shall be settled by the President of the Office for Registration of Medicinal Products, Medical Devices, and Biocides, hereinafter referred to as "the Office President". Chapter 4 Essential requirements and assessment of medical device conformity with the essential requirements
Article 16.
1. A medical device being placed on the market and put into service must comply with the essential requirements which apply to it. 2. Prior to placing on the market and putting into service of a medical device, a manufacturer or his authorised representative shall ensure that it has undergone a procedure of assessment of conformity with the essential requirements applicable to that device.

Article 17.
It shall be presumed that there is a compliance with the essential requirements in respect of medical devices which are in conformity with:
1)domestic standards adopted on the basis of harmonised European standards for active implantable medical devices, in vitro diagnosis medical devices, and medical devices for various purposes
2) monograph elaboration of the European Pharmacopaeia on surgical threads and materials intended for storage of medicinal products for medical devices for various purposes
3) common technical specifications for in vitro diagnosis medical devices.

Article 18.
The manufacturer, his authorised representative, importer or the entity responsible for placing the medical device on the market shall safe-keep the conformity assessment documentation for the medical device for the period of 5 years from the production cessation date.

Article 19.
The minister competent for health shall, by Regulation, determine, for medical devices for various purposes: 1) essential requirements
2) conformity assessment procedures
3) detailed technical specifications for medical devices manufactured utilising animal tissues
4) the list of conformity assessment procedures that may be conducted by an authorised representative - taking into consideration the classification and intended purpose of the device, the manufacturer's quality system, as well as safety and protection of patients' life and health.

Article 20.
The minister competent for health shall, by Regulation, determine, for in vitro diagnostic medical devices: 1) the essential requirements
2) lists A and B
3) conformity assessment procedures
4) the list of conformity assessment procedures that can be conducted by the authorised representative - taking into consideration the qualification and intended purpose of the device, manufacturer's quality system, as well as safety and protection of patients' life and health.

Article 21.
The minister competent for health shall, by Regulation, determine, for active implantable medical devices: 1) essential requirements
2) conformity assessment procedures
3) the list of conformity assessment procedures that may be conducted by an authorised representative - taking into consideration the intended purpose of the device, the manufacturer's quality system, as well as safety and protection of patients' life and health

Article 22.
The conformity assessment procedure of:
1)Class I medical devices with a measuring function
2) Class I sterile medical devices
3) sterile systems and procedure packs
4) Class IIa medical devices
5) Class IIb medical devices
6) Class III medical devices
7) active implantable medical devices
8) in vitro diagnosis medical devices from A list
9) in vitro diagnosis medical devices from B list
10) in vitro diagnosis medical devices for self-testing - shall be conducted by the manufacturer with the participation of the notified body competent for the scope of notification on the basis of a contract concluded.

Article 23.
1. The medical device documentation concerning conformity assessment procedures conducted within the territory of the Republic of Poland and the correspondence between the manufacturer or his authorised representative and the notified body authorised by the minister competent for health shall be kept and conducted in the Polish language. 2. Upon a consent of the notified body, the documentation and correspondence on the conformity assessment procedures conducted within the territory of the Republic of Poland may be submitted to this notified body in a language other than Polish.

Article 24.
1. The notified body may demand that the manufacturer or his authorised representative make available the technical documentation and the information necessary to perform the acts covered by the procedure for assessment of the medical device conformity with the essential requirements. 2. The notified body and the subcontractor acting upon order from this body and participating in the conformity assessment of medical devices shall be obliged to keep secret the information obtained in the course of relevant procedures.

Article 25.
During the medical device conformity assessment procedure, the manufacturer, his authorised representative or the notified body shall take into consideration the outcome of device assessment and verification received at the production stage.

Article 26.
1. After conducting the conformity assessment to the extent defined in the contract, the notified body authorised by the minister competent for health shall issue a certificate confirming the fulfilment of the requirements which is valid a 5-year period or refuse to issue such certificate. 2.

In case of refusal to issue the certificate referred to in paragraph 1, the body shall formulate the grounds for this refusal and submit them to the manufacturer or his authorised representatives. 3. Where a notified body authorised by the minister competent for health finds that the manufacturer ceased to meet the requirements for the issue of a certificate, it shall annul, suspend or limit the scope of certification, appropriately to the level of risk resulting from non-fulfilment of these requirements. 4. In the case of suspension of the certificate or limiting its scope, the notified body shall determine the conditions for withdrawal, limitation or suspension of certificate, until the manufacturer ensures that the requirements are met by taking appropriate corrective measures. 5. The notified body referred to in paragraph 1 shall notify: 1) the minister competent for health of:

a) suspension, withdrawal, and limitation of the scope of certification

b) certificates issued or refusals to issue the same – on his request

c) other circumstances, if these require intervention of a competent authority

2) other notified bodies of:

a) suspension, withdrawal, and limitation of the scope of certification

b) certificates issued or refusals to issue the same – on their request. 6. The notified body shall make available to the minister competent for health or other notified bodies, on their request, any additional information on certificates or refusals to issue the same. 7. The minister competent for health shall notify other authorities of the European Union Member States or the European Free Trade Agreement (EFT a) Member States, being parties to the European Economic Area Agreement, competent for medical devices, and also the European Commission of any certificates suspended, withdrawn, or limited in their scope. Chapter 5 Notified bodies

Article 27.

1. A notified body shall be the body that has an identification number assigned by the European Commission and was put on the list of bodies published in the Official Journal of the European Communities. 2. In order to become notified for medical devices, a body must obtain an authorisation of a competent authority. 3. The authority competent for authorisation in the territory of the Republic of Poland shall be the minister competent for health. 4. Authorisation shall be granted by the minister competent for health by a decision, upon application of a body meeting the requirements defined in paragraph 6. 5. In a decision on authorisation the minister competent for health shall determine the scope of authorisation of the notified body for specific medical devices. 6. A body applying for authorisation shall: 1) have the staff with suitable knowledge on medical devices and conformity assessment procedures for specific medical devices

2) be independent and impartial in relation to entities directly and indirectly related to the process of medical device manufacturing

3) ensure the compliance with regulations on protection of confidential information and other information protected by the law

4) be insured against civil liability in the amount adequate to the risk related to the activity conducted. 7. An application for authorisation shall contain: 1) the name and registered office address of the body applying for authorisation

2) scope of authorisation. 8. The application for authorisation shall be accompanied by documents confirming the fulfilment of the requirements referred to in paragraph 6. 9. The minister competent for health shall, by a decision, withdraw the authorisation or limit its scope, if he finds that the authorisation conditions referred to in paragraph 6 were violated. 10. Scope of authorisation shall be limited to the extent to which the notified body lost its capability to perform the tasks specified in the authorisation. 11. The minister competent for health shall, by Regulation, determine the detailed requirements to be met by the bodies applying for authorisation to become notified bodies for medical devices, taking into consideration the European Union regulations on medical devices.

Article 28.

1. The minister competent for health shall notify the minister competent for economy of the authorised bodies in order to notify them to the European Commission and the European Union Member States or the European Free Trade Agreement (EFT a) Member States, being parties to the European Economic Area Agreement. 2. In case of withdrawal or limitation of authorisation the minister competent for health shall notify the same to the minister competent for economy who shall in turn notify this decision to the European Commission and the European Union Member States or the European Free Trade Agreement (EFT a) Member States, being parties to the European Economic Area Agreement. 3. The minister competent for economy shall publish the information on notified bodies authorised by the minister competent for health as notified bodies for medical devices as well as on withdrawal of authorisation or changing its scope, in the form of announcement in the Official Gazette of the Republic of Poland "Monitor Polski".

Article 29.

1. The minister competent for health shall exercise the surveillance of notified bodies in respect of the fulfilment of the requirements specified in Article 27. 2. The control acts forming the part of the surveillance referred to in paragraph 1 shall be conducted on the basis of a written authorisation issued by the minister competent for health, specifying: 1) the controlling person
2) name of the notified body controlled
3) scope of control and its anticipated duration. 3. Persons authorised by the minister competent for health to perform the control shall be entitled to: 1) enter the area, premises and rooms of the notified body on its working days and during its working hours
2) demand verbal and written explanations and the presentation of documents related to the activity covered by the notification
3) demand the notified body to furnish, within the time limit defined, verbal and written explanations on issues covered by the control. 4. Control acts shall be performed in the presence of the controlled entity or the person it has authorised. 5. Minutes of the control shall be drawn up and submitted to the controlled notified body. Chapter 6 Clinical evaluation of medical devices for various purposes and active implantable medical devices

Article 30.

1. A manufacturer or its authorised representative shall perform clinical evaluation of a medical device for various purposes or active implantable medical device in order to verify that, under normal conditions of use, it conforms to the essential requirements applicable to it, and to assess any undesirable side effects. 2. Clinical evaluation of a medical device for various purposes or active implantable medical device shall be performed on the basis of: 1) combined data derived from relevant scientific literature currently available on the intended purpose of the device and the techniques applied
or 2) written study including a critical evaluation of such combined data
or 3) results of clinical investigations performed in compliance with the provisions hereof. 3. Clinical investigation of a medical device for various purposes and active implantable medical device shall be performed if the data referred to in paragraph 2, subparagraphs 1 and 2 are not sufficient to perform the clinical evaluation. 4. Clinical investigation of a medical device for various purposes and active implantable medical device shall be deemed a medical experiment with a medical device performed on humans as defined in the provisions of Chapter 4 of the Act of 5 December 1996 on the profession of a doctor.

Article 31.

Clinical investigation of a medical device for various purposes and active implantable medical device, hereinafter referred to as "the clinical investigation", shall be performed in order to: 1)

confirm that, under normal conditions of use, parameters of performance of a medical device as intended by the manufacturer are compliant with the essential requirements
2) find, under normal conditions of use, any undesirable side effects of a medical device and to assess whether the anticipated result of performance of the device outweigh the risk connected with such performance

Article 32.
The condition for commencement of clinical investigation shall be a positive opinion of the bioethical commission referred to in Article 29 of the Act of 5 December 1996 on the profession of a doctor (Journal of Laws 2002, No. 21, item 204, as amended2)) and a permit of the Office President, subject to Article 38.

Article 33.
1. Clinical investigation shall:
1)be performed in such a way so as to confirm or question the device properties declared by its manufacturer
2) cover the appropriate number of observations which guarantees that the conclusions are scientifically grounded
3) be performed under the conditions similar to the normal conditions of use of the device
4) refer to all relevant properties, including those related to the device safety and functionality and its performance on investigation participants
5) ensure that the procedures employed for performing the clinical investigation are properly chosen for the medical device undergoing such investigation
6) ensure that the investigator has access to technical and clinical data concerning the device
7) be preceded by a proper conformity assessment procedure with respect to medical devices submitted for clinical investigation. 2. The form of planning, carrying out, monitoring, documenting, and reporting the results of clinical investigations and the duties of the parties participating in the investigation or applying for its performance shall be compliant with the European harmonised standards referred to in Article 17 or with the national standards incorporating such European harmonised standards.

Article 34.
To the extent which is not specifically regulated herein, clinical investigation shall be governed by the provisions of Chapter 4 of the Act of 5 December 1996 on the profession of a doctor.

Article 35.
1. In order to obtain the permit referred to in Article 32, the sponsor shall apply to Office President for a permit to commence the clinical investigation. 2. A fee shall be charged for examination of the application for a permit to commence the clinical investigation. 3. The application referred to in paragraph 1 shall be deemed filed on the date of its delivery. 4. The application referred to in paragraph 1 shall be accompanied by: 1) the data of the medical device intended for clinical investigation
2) the clinical investigation protocol which is a document describing the objectives, plan, methodology, statistics, and organisation of the clinical investigation
3) information for the patient and a specimen conscious consent
4) rules of the clinical investigation insurance
5) clinical observations chart
6) data of investigators and centres participating in the clinical investigation
7) a positive opinion from the bioethical commission

8) declaration of compliance of the medical device intended for clinical investigation with safety requirements, confirming that the device complies with essential requirements beyond the issues covered by the clinical investigation
9) receipt of payment of the fee for examination of application. 5. The Office President shall, by a decision, issue a permit to commence the clinical investigation of a medical device whose performance is based on new physical or chemical phenomena, having consulted the Commission for Medical Devices as referred to in the Act of 27 July 2001 on the Office for Registration of Medicinal Products, Medical Devices, and Biocides (Journal of Laws 2001, No. 126, item 1397 and 2002
No. 152, item 1263). 6. The minister competent for health shall, by Regulation, determine: 1) specimen application for a permit to commence the clinical investigation and the list of documents to be attached thereto
2) specimen declaration of compliance of the medical device intended for clinical investigation with safety requirements
3) the amount of fee charged for examination of the application referred to in subparagraph 1
4) the data to be included in the final report from clinical investigation - taking into consideration the European Union legislation on medical devices, the amounts of fees collected in other European Union Member States of similar gross domestic product per capita, the effort required to perform a given act, and the level of costs borne by the Office President.

Article 36.
If the clinical investigation of a device fails to comply with the requirements specified in Articles 31 to 34, the Office President shall issue a decision refusing to issue a permit to commence the clinical investigation.

Article 37.
The Office President shall enter the clinical investigation whose commencement he permitted and the clinical investigations referred to in

Article 38 into the Central Records of Clinical Investigations referred to in the provisions of the Act of 6 September 2001 – Pharmaceutical Law (Journal of Laws 2004, No. 53, item 533, No. 69, item 625, No. 91, item 877, and No. 92, item 822).

Article 38.
1. In case of Class III medical devices for various purposes, as well as implantable medical devices for various purposes, and invasive medical devices belonging to Class IIa or IIb, whose time of continuous use exceeds 30 days, and active implantable medical devices the lack of refusal to issue a permit to commence the clinical investigation within 60 days after the date of filing the application referred to in Article 35, paragraph 1 shall be deemed the issue of such permit, provided that the bioethical commission issued a positive opinion on the clinical investigation. 2. In case of medical devices other than mentioned in paragraph 1, the lack of refusal to issue a permit to commence the clinical investigation within 14 days after the date of filing the application referred to in Article 35, paragraph 1 shall be deemed the issue of such permit, provided that the bioethical commission issued a positive opinion on the clinical investigation.

Article 39.
1. The clinical investigation shall be carried out on the basis of contracts concluded between the sponsor and the entities performing the clinical investigations. 2. Entities performing the clinical

investigation shall enable the sponsor to control the clinical investigation. 3. The investigation shall be controlled by the sponsor on terms stipulated in the contracts referred to in paragraph 1.

Article 40.
Medical investigation performed with medical devices with a CE-marking affixed on the basis of relevant conformity assessment procedures shall not be considered clinical investigation, unless the object of such medical investigation is the medical device application other than intended by the manufacturer and specified in the conformity assessment procedure.

Article 41.
1. The bioethical commission shall give its opinion to the applicant within 60 days. 2. The period referred to in paragraph 1 shall run from the date of filing the complete documentation and may be extended by no more than 30 days in case of clinical investigation of a medical devices whose performance is based on new physical or chemical phenomena. 3. During the application examination the bioethical commission may demand the applicant once to furnish the information supplementing the information already contained in the documentation. The running of the period referred to in Article 38, paragraph 1 shall be suspended until such supplementing information is furnished.

Article 42.
The opinion of the bioethical commission may be appealed against to the Appeal Bioethical Commission as referred to in Article 29 of the Act of 5 December 1996 on the profession of a doctor.

Article 43.
1. The sponsor may modify the protocol after commencing the clinical investigations, but if such modifications are significant and may affect the safety of investigation participants, the sponsor shall obtain a permit from the Office President and opinion of the bioethical commission which previously gave its opinion on the clinical investigation. 2. The permit of the Office President and the opinion of the bioethical commission as referred to in paragraph 1 shall be respectively governed by the provisions on issue of opinion and permit to perform the clinical investigation, provided that the time limit for giving the opinion and issuing the permit shall be 30 days.

Article 44.
1. In case of any new effects that might affect the safety of the investigation participants, the sponsor or investigator shall refrain from the clinical investigation as per the protocol in force. In such case, the sponsor and investigator shall undertake appropriate measures aimed to ensure the investigation participants' safety. 2. The sponsor shall immediately notify the effect and the measures undertaken to the Office President and to the bioethical commission which gave its opinion on the investigation.

Article 45.
1. The investigator shall be responsible for performing the investigation in a specific centre, and it shall ensure medical care for the clinical investigation participants. 2. The investigator shall immediately notify to the sponsor any serious side effect construed. 3. Any side effect other than listed in paragraph 2 shall be reported to the sponsor in the form determined in the clinical investigation protocol. 4. Immediately, but in any case not later than within 7 days after the occurrence of a serious side effect, the sponsor shall forward such information to the Office President and the bioethical commission which gave its opinion on the investigation. 5. In case of a serious side effect, the investigator, on request from the sponsor, the Office President or the

bioethical commission, shall submit any available information that has not been contained in the previous information on the side effect. 6. The sponsor shall safe-keep the documentation on effects referred to in paragraphs 2 and 3 and render it available on request of the Office President. 7. The sponsor shall notify the serious undesirable side effects to all investigators performing the clinical investigation. 8. The Office President shall collect the data on undesirable side effects occurring in connection with performance of clinical investigation in the territory of the Republic of Poland.

Article 46.

1. Within 90 days after the clinical investigation completion, the sponsor shall send to the Office President and the bioethical commission, which gave its opinion on the investigation, a final report on the clinical investigation, hereinafter referred to as "the report", being a comprehensive description of the clinical investigation executed after its completion. 2. The report shall include the description of methodology and design, data analysis, as well as their critical evaluation and statistical analysis, if any, and clinical evaluation. 3. The report shall be signed by all investigators, and in case of a refusal to sign, the refusing investigator shall state the reasons for such decision. 4. The report shall be executed taking into consideration all data from all centres and on all the patients. 5. The report cannot enable identification of personal data of the investigation participants. 6. If the investigation is completed before the end of the time limit declared, the sponsor shall notify such fact within 15 days to the Office President and the bioethical commission, which gave its opinion on the investigation, stating the reasons for such earlier completion. 7. On the sponsor's request, the Office President shall issue a decision on suspension or discontinuance of clinical investigation.

Article 47.

1. Any data related to the investigation participants and collected during the clinical investigation shall be treated as confidential. 2. Any documents and records related to the clinical investigation:
1) shall be safe-kept for at least 20 years after the clinical investigation completion
2) shall be rendered available for inspection to the Office President or to the competent bioethical commission at their request.

Article 48.

1. In case of a grounded suspicion that the conditions specified in the permit for clinical investigation are no longer met or upon receiving information questioning the safety or scientific grounds for the clinical investigation, the Office President may, by a decision, suspend the clinical investigation, recall the permit for the clinical investigation, or specify the measures to be undertaken if the clinical investigation is to be continued. 2. If there is no direct threat to the safety of clinical investigation participants, the Office President shall, prior to issue of the decision referred to in paragraph 1, apply to the sponsor and investigator for responding to his objections within 7 days. 3. The Office President shall notify his decision referred to in paragraph 1 to the sponsor, the bioethical commission, which gave its opinion on the investigation and, if the investigation was also carried out in the territory of other states, to competent authorities of such other states.

Article 49.

Importation of medical devices intended for clinical investigations from outside the territory of the European Union Member States or the European Free Trade Agreement (EFT a) Member States, being parties to the European Economic Area Agreement shall require a certificate issued by the Office President to the investigator by a decision, after a permit for clinical investigation is obtained.

Article 50.

1. The control of clinical investigations shall be performed by the Clinical Investigation Inspection Office as referred to in the Pharmaceutical Law Act. 2. The control referred to in paragraph 1 shall be performed by a person authorised by the Office President, hereinafter referred to as the "controller". 3. The controller may, in particular:

1)control the centres performing clinical investigations, the sponsor's seat, seat of an organisation performing the clinical investigation to order or other places considered relevant from the point of view of clinical investigation

2) demand the submission of documentation related to the investigation pending

3) demand providing the explanations related to the investigation performed and the documentation submitted. Chapter 7 Registers of medical devices and entities responsible for their placing on the market and putting into service

Article 51.

1. The Office President shall keep a Register of medical devices and entities responsible for their placing on the market and putting into service, hereinafter referred to as "the Register". 2. The Register shall be kept in the form of electronic carriers of information and protected against access of unauthorised parties. 3. The Register shall be composed of two parts: 1) part I – containing the name and address of the entity authorised to place on the market and put into service the medical devices, identification number of notification, and the identification number assigned to the entity in the Register in the territory of the Republic of Poland, formed as PL/CA01/ subsequent number of entry of the entity authorised in the Register

2) part II – containing:

a) trade name under which the medical device is placed on the market or put into service in the territory of the Republic of Poland, other trade names under which it is sold in the territory of the European Union Member States or the European Free Trade Agreement (EFT a) Member States, being parties to the European Economic Area Agreement, and the identification number assigned to the medical device in the Register

b) the technical and medical name of the device

c) the device class, kind or type

d) intended purposes of the medical device

e) identification number of the notified body which participated in the conformity assessment of the medical device.

Article 52.

1. Manufacturers, authorised representatives, importers, entities responsible for placing medical devices on the market, entities assembling medical devices, and entities performing the sterilisation referred to in

Article 8 and established within the territory of the Republic of Poland shall make a notification to the Register of a medical device for various purposes or an active implantable medical device prior to its placing on the market or putting into service for the first time. 2. Manufacturers, authorised representatives or importers established within the territory of the Republic of Poland shall make a notification to the Register of an in vitro diagnostic medical device prior to its placing on the market or putting into service for the first time.

Article 53.
A manufacturer performing custom-made medical devices established within the territory of the Republic of Poland shall notify to the Register exclusively the data determined in part I as referred to in Article 51, paragraph 3, paragraph 1, and the information on the types of medical devices manufactured.

Article 54.
1. Manufacturer, his authorised representative, importer or entity responsible for placing medical devices on the market, which places on the the territory of the Republic of Poland an active implantable medical device, Class IIb or Class III medical device, in vitro diagnostic medical device from list A or list B or in vitro diagnostic medical device for self-testing shall make a notification to the Register immediately after putting the medical device into service for the first time. 2. The notification duty referred to in paragraph 1 shall not apply to an authorised entity which made a notification to the Register pursuant to

Article 52.

Article 55.
1. In case of in vitro diagnosis medial devices, notification to the Register shall contain: 1) the name and address of the entity authorised for placing medical devices on the market and putting them into service
2) description of the device. 2. In case of in vitro diagnostic medical devices such as reagents, reagent products, control materials, and calibrators, a notification to the Register shall contain the data referred to in paragraph 1 and the code of common technological characteristics or the name of analyte. 3. In case of in vitro diagnostic medical devices from list A or list B and in vitro diagnostic medical devices for self-testing, a notification to the Register shall contain: 1) the data referred to in paragraph 1
2) analytical and diagnostic parameters:
a) analytical sensitivity
b) diagnostic sensitivity
c) analytical specificity
d) diagnostic specificity
e) accuracy
f) repeatability
g) reproducibility - including control of known relevant interference and limits of detection
3) performance evaluation outcome for the medical device
4) number of the notified body, if it participated in the conformity assessment and a copy of the certificate issued by this body
5) specimen labelling and instructions for use to accompany the device being placed on the market in the territory of the Republic of Poland and specimen labelling and instructions for use submitted to the notified body. 4. In case of a new device or in vitro diagnostic medical device for performance evaluation, a notification to the Register shall contain the data referred to in paragraph 1 and the data referred to in paragraph 2 or 3, respectively.

Article 56.
In case of a medical device other than an in vitro diagnostic medical device or a custom-made medical device, a notification to the Register shall contain: 1) name and address of the entity authorised to place medical devices on the market and put them into service
2) description and application of the medical device

3) number of the notified body, if it participated in the conformity assessment and a copy of the certificate issued by this body
4) specimen labelling and instructions for use to accompany the device being placed on the market and put into service in the territory of the Republic of Poland and specimen labelling and instructions for use submitted to the notified body.

Article 57.
Any modifications to the data contained in the Register and the discontinuation of placing on the market or putting into service of the medical device shall be reported to the Office President by the entities referred to in Articles 52 and 54.

Article 58.
The minister competent for health shall, by Regulation, determine the specimen forms used for notifications to the Register and the procedure for transferring the data included in the notification forms, taking into consideration the scope of data referred to in Articles 55 and 56 and the European Union regulations on medical devices.

Article 59.
1. A fee shall be collected for notification to the Register and for modification of data contained in the Register. 2. The minister competent for health shall, by Regulation, determine the amount of fee for for notification to the Register and for modification of data contained in the Register, taking into consideration the type of medical product notified, the amounts of fees collected in other European Union Member States of similar gross domestic product per capita, the effort required to perform a given act, and the level of costs borne by the Office President.

Article 60.
The Register shall be rendered available on request, subject to the regulations on personal data and trade secret protection. Chapter 8 Medical incidents
Article 61.
1. Medical incidents involving medical devices, hereinafter referred to as “medical incidents”, which took place in the territory of the Republic of Poland shall be reported to the Office President, and, where possible, to manufacturer, his authorised representative, distributor, importer or entity responsible for placing the medical device on the market. 2. The Office President shall keep a Register of Medical Incidents. 3. The Register referred to in paragraph 2 shall contain, in particular: 1) date, place, and description of a medical incident
2) name, registered office address, and identification number of the manufacturer or his authorised representative
3) commercial as well as technical and medical name of the medical device, its intended purpose and classification
4) series number or the number of a batch of medical device
5) number of the notified body.

Article 62.
1. The duty to report medical incidents shall apply to manufacturers, their authorised representatives, distributors, importers, entities responsible for placing medical devices on the market, health care centres, medical staff, inspection authorities, and the centres conducting external quality control systems for diagnostic laboratories that encounter medical incidents while conducting their activity. 2. A notification of medical incident shall contain the data referred to in

Article 61, paragraph 3 and, in particular, the type, size, results of medical incident, as well as full name and profession of the person reporting this incident. 3. A medical incident may be reported by anyone who became aware thereof.

Article 63.
The Office President shall notify the medical incident reported to the manufacturer or his authorised representative, unless they were the reporting parties.

Article 64.
1. After being notified about a medical incident, the manufacturer or his authorised representative shall prepare the Initial Report, containing in particular the data of the party reporting the medical incident, the data of the manufacturer, information on the device, description of the medical incident, its date, place and results, as well as corrective and preventive measures stipulated and their schedule. 2. The Initial Report shall be verified by the Office President.

Article 65.
1. The Office President shall conduct the assessment of the medical incident together with the manufacturer or his authorised representative. 2. The Office President shall assess the measures undertaken by the manufacturer or his authorised representative. If he considers them insufficient, he shall undertake acts aimed to explain the medical incident. 3. The Office President may, by decision, suspend the use or placing on the market and putting into service of a medical device due to a significant threat to the health or life of a patient, use or a third party.

Article 66.
1. After completing the acts aimed to explain the reasons for a medical incident, the manufacturer or his authorised representative shall prepare the Final Report together with the documentation explaining the reasons for the medical incident. 2. If the manufacturer or his authorised representative have not prepared the Final Report, it shall be drawn up by the Office President, who shall provide detailed reasons for preparing the same and submit the Report to the manufacturer.

Article 67.
1. The Office President shall prepare a Competent Authority Report if he ascertains that a medical device poses a threat to the health or life of a patient, use or a third party. 2. The Report referred to in paragraph 1 shall, in particular, contain information on: 1) recalling a medical device from the market
2) recalling a medical device from the market and from service
3) suspending the placing on the market and putting into service of a medical device
4) restrictions in marketing or service of a medical device. 3. The Office President shall immediately notify the President of the Office for Competition and Consumers Protection of the issue of the decisions referred to in paragraph 2, in order to render available the information on restrictions in marketing and service of specific medical devices in the national system of information on hazardous products. 4. The Report referred to in paragraph 2 shall be prepared in the Polish and English language. 5. The Office President shall notify the authorities competent for medical devices in the European Union Member States and the European Free Trade Agreement (EFT a) Member States, being parties to the European Economic Area Agreement, of occurrence of a medical incident, sending the Competent Authority Report.

Article 68.
The minister competent for health shall, by Regulation, determine:

1)the procedure for reporting medical incidents by entities obliged to do so
2) detailed procedure for entities conducting acts aimed to explain medical incidents
3) specimen form of medical incident notification
4) specimen Initial Report form
5) specimen Final Report form
6) specimen Competent Authority Report form - taking into consideration the scope of information specified in Article 61, paragraph 3, the European Union regulations on medical devices, and the European Commission regulations in the part pertaining to medical incidents. Chapter 9 Surveillance over medical devices placed on market and put into service

Article 69.

1. The surveillance over medical devices manufactured or placed on the market and put into service within the territory of the Republic of Poland shall be exercised by the Office President. 2. The Office President shall perform its tasks with the assistance of: 1) the Main Pharmaceutical Inspector
2) the Main Sanitary Inspector
3) the Main Veterinary Doctor
4) the Main Inspector of the Trade Inspection Office
5) the Head of the Customs Service
6) the President of the Technical Supervision Office
7) the Main Labour Inspector
8) the President of the State Atomic Agency
- to the extent appropriate for these bodies. 3. The authorities referred to in paragraph 2 shall notify the Office President of ascertained irregularities related to medical devices. 4. The surveillance referred to in paragraph 1 shall include the control of design, manufacture, packaging, labelling, storage, assembly, distribution, processing, full refurbishment, and display of medical devices, assigning their intended application to them, sterilisation before placing on the market and putting into service, arranging the devices in systems or procedure packs, as well as of the placing on the market and putting into service of medical devices in the territory of the Republic of Poland.

Article 70.

1. The control exercised by the Office President shall be performed by persons he authorises. 2. The control shall be performed during working hours of the controlled entity and in the presence of the person this entity has authorised. 3. As a part of the control, the controller may, in particular: 1) inspect the documentation concerning the conformity assessment of the medical device
2) examine the acts concerning the medical device, including its design, manufacture, packaging, labelling, control, final testing, storage, and distribution.

Article 71.

1. Minutes shall be drawn up from the control conducted, which may contain post-control recommendations and comments of the authorised representative of the controlled entity. 2. The minutes referred to in paragraph 1 shall be signed by the controller and the authorised representative of the controlled entity. 3. The controlled entity shall implement the post-control recommendations within the time limit specified in the minutes.

Article 72.

1. In case of being notified that a medical device fails to meet the relevant requirements, the Office President may: 1) demand that manufacturer, his authorised representative, distributor or importer make available medical device samples necessary to conduct its testing and verification

2) order that the samples referred to in subparagraph 1 be tested by research and development entities, scientific institutes, academies, device certifying entities or laboratories. 2. If the outcome of testing and verification referred to in paragraph 1 confirms that a device fails to meet the relevant requirements, the costs of such testing and verification shall be paid by the manufacturer, his authorised representative, distributor, importer or a person responsible for placing the device on the market.

Article 73.

If the outcome of testing and verification referred to in Article 72, paragraph 1 or the outcome of control referred to in Article 70 confirms that a medical device fails to meet the relevant requirements or the post-control recommendations referred to in Article 71, paragraph 1 have not been implemented, the Office President, taking into consideration the potential threat to life and health of patients, users, and third parties, shall respectively issue a decision: 1) obliging the authorised entity to publish an advisory note, containing a warning issued in order to furnish information or recommendations concerning the measures to be taken during use, modification, disposal or return of the medical device

2) suspending the placing on the market and putting into service of the device

3) restricting the marketing or use of the device

4) recalling the device from the market

5) recalling the device from the market and service.

Article 74.

1. In case of a grounded suspicion that the device, after having been installed correctly, during correct operation or during its use in accordance with the intended purpose, poses threat to life, health or safety of patients, users or third parties, the Office President shall immediately undertake measures aimed to find: 1) reasons for the existing threat to human life or health

2) persons responsible for the irregularities ascertained. 2. In the case referred to in paragraph 1, the Office President shall issue a decision on: 1) suspension of the placing on the market and putting into service of the device

or 2) restricting the marketing or use of the device. 3. If it is ascertained that the device, after having been installed correctly, during correct operation or during its use in accordance with the intended purpose, poses threat to life, health or safety of patients, users or third parties, the Office President shall issue a decision: 1) obliging the authorised entity to publish an advisory note, containing a warning issued in order to furnish information or recommendations concerning the measures to be taken during use, modification, disposal or return of the medical device

2) recalling the device from the market and service. 4. Manufacturer or his authorised representative shall be entitled to submit to the Office President relevant explanations which shall be take into consideration prior to making the decision referred to in paragraph 2, unless it is impossible because of an urgent need of taking appropriate measures due to a threat to health or life of patients, users or third parties.

Article 75.

1. In case of suspension of placing on the market and putting into service of a device, recalling a device from the market and service, or restricting the use of a device, respective notification shall be made by the Office President, manufacturer, authorised representative, distributor, importer or the entity responsible placing the device on the market. 2. The costs of notification referred to in paragraph 1 shall be paid by the notifying party.

Article 76.

The acts connected with recalling a medical device from the market and service, or restricting the marketi8ng and service of a device in the territory of the Republic of Poland shall be performed

and their costs shall be paid by the manufacturer, authorised representative, importer or distributor established in the territory of the Republic of Poland.

Article 77.
The Office President shall notify the decisions referred to in Articles 73 and 74 to the European Commission and authorities of other European Union Member States and the European Free Trade Agreement (EFT a) Member States, being parties to the European Economic Area Agreement, competent for medical devices, stating the grounds for his decisions, relating in particular to: 1) non-fulfilment of the essential requirements
2) incorrect application of harmonised standards
3) mistakes in harmonised standards.
Chapter 10 Penal provisions
Article 78.
Whoever places on the market and puts into services the medical device which has not undergone the relevant conformity assessment, shall be punished with a fine, limitation of liberty or imprisonment for up to 2 years.

Article 79.
Whoever, in contravention of the conditions specified in this Act, places on the market and puts into services the systems and procedure packs or sterilises such systems and procedure packs or other medical devices for various purposes bearing a CE marking, shall be punished with a fine or imprisonment for up to 2 years, or both penalties.

Article 80.
Whoever conducts clinical investigations of a medical device without a required permit or in contravention of the conditions specified in this Act shall be punished with a fine, limitation of liberty or imprisonment for up to 2 years.

Article 81.
Whoever markets on the territory of the Republic of Poland a medical device without marking, instructions for use or labelling in the Polish language referred to in Article 4, paragraph 5, shall be punished with a fine.

Article 82.
1. Whoever, in contravention of the conditions specified in this Act, commits an unauthorised marking of a device with a CE mark or with a notified body's identification number shall be punished with a fine. 2. The same penalty shall apply to whoever applies marks and inscriptions which are likely to be misleading as to CE marking or a notified body's identification number.

Article 83.
1. Whoever places on the market or puts into service a medical device whose validity period expired, shall be punished with a fine. 2. The same penalty shall apply to whoever places on the market or puts into service a medical device whose marking or instructions for use might be misleading as to the characteristics or performance of this device.

Article 84.
Whoever fails to make a notification to the Register or notify the modifications referred to in Article 57 shall be punished with a fine.

Article 85.

Whoever fails to notify an incident involving a medical device referred to in Article 62 shall be punished with a fine, limitation of liberty or imprisonment for up to 1 year.

Article 86.
Whoever renders it difficult or impossible for the person authorised by the Office President to conduct the control referred to in Article 70 shall be punished with a fine, limitation of liberty or imprisonment for up to 2 years. Chapter 11 Amendments to the provisions in force transitional and final provisions

Article 87.
In the Act of 11 May 2001 – Law on Measures (Journal of Laws 2001, No. 63, item 636, as amended3)), in Article 2, paragraph 3 shall be added, reading: "3. The provisions of this Act shall not apply to devices being medical devices as defined in the Act of 20 April 2004 on medical devices (Journal of Laws 2004, No. 93, item 896)."

Article 88.
In the Act of 27 July 2001 on the Office for Registration of Medicinal Products, Medical Devices, and Biocides (Journal of Laws 2001, No. 126, item 1397 and 2002 No. 152, item 1263), the following amendments shall be made: 1) in Article 1 in paragraph 2, subparagraph 2 shall be repealed
2) after Article 5, Articles 5a and 5b shall be added, reading
"Article 5a. 1. The Office President shall issue decisions on cases related to medical devices specified in the Act of 20 April 2004 on medical devices (Journal of Laws 2004, No. 93, item 896). 2. In cases in which the Office President issues its decisions as the authority of first instance, the authority of higher instance shall be the minister competent for health. 3. The Office President shall perform its tasks in the scope of medical devices through the Office. Article 5b. The tasks of the Office President in the field of medical devices shall include, in particular: 1) keeping of the Register of medical devices and entities responsible for their placing on the market and putting into service
2) keeping of the Register of Medical Incidents
3) making entries of clinical investigations in the Central Records of Clinical Investigations
4) exercising supervision over medical devices manufactured, placed on the market and put into service in the territory of the Republic of Poland
5) conducting the control over clinical investigations
6) conducting the assessment of medical incidents
7) notifying the decisions on suspending the use, placing on the market or putting into service of medical devices, which compromise the safety of use, to the European Commission and authorities of other European Union Member States or the European Free Trade Agreement (EFT a) Member States, being parties to the European Economic Area Agreement, competent for medical devices
8) notifying the recalling from market and service of medical devices to the European Commission and authorities of other European Union Member States or the European Free Trade Agreement (EFT a) Member States, being parties to the European Economic Area Agreement, competent for medical devices." 3) in Article 6, in paragraph 1, subparagraph 2 shall be repealed.
Article 89.
The Act of 6 September 2001 – Pharmaceutical Law (Journal of Laws 2004, No. 53, item 533, No. 69, item 625, No. 91, item 877, and No. 92, item 822) shall be amended as follows: 1) in Article 67, paragraph 2 shall be amended to read: "2. Medicinal products referred to in paragraph 1 shall

be disposed, subject to Article 122, paragraph 1, subparagraph 2." 2) in Article 70, paragraph 5 shall be amended to read: "5. To the extent of storing and keeping the documentation of medicinal products purchased and sold as well as the form and procedure for performing the control of accepting medicinal products and the rules and procedure for forwarding information on trading in and stocks of particular medicinal products, provisions of law on pharmacies shall respectively apply." 3) in Article 78, in paragraph 1, subparagraph 1 shall be amended to read: "1) the purchase of medicinal products exclusively from entrepreneurs dealing with manufacture or wholesale trading
" 4) in Article 88, in paragraph 5, subparagraph 5 shall be amended to read: "5) the purchase of medicinal products exclusively from entities holding a permit to run a pharmaceutical warehouse and their release pursuant to

Article 96
" 5) in Article 108, in paragraph 4:
a) subparagraphs 1 and 2 shall be amended to read: "1) suspension or recalling from market or service in health care centres of medicinal products in case of suspecting or finding that a product was not admitted to trading in Poland
2) suspension or recalling from market or service in health care centres of medicinal products in case of suspecting or finding that a product is non-compliant with qualitative requirements that apply to it
b) subparagraphs 4 and 5 shall be amended to read: "4) granting, amending, recalling or refusing to grant a permit:
a) to run a pharmacy
b) to manufacture medicinal products
c) to deal with wholesale trading in medicinal products
5) referring a medicinal product admitted to trading in the territory of the Republic of Poland for quality examinations." c) subparagraph 6 shall be repealed
6) in Article 109, subparagraphs 2 and 3 shall be amended to read: "2) exercising supervision over the quality of medicinal products traded in
3) controlling pharmacies and other entities dealing with retail and wholesale trading in medicinal products and medical devices referred to in

Article 108, paragraph 1
" 7) in Article 121:
a) paragraphs 1 to3 shall be amended to read: "1. In case of a grounded suspicion that a medicinal product fails to meet the requirements that apply to it, the provincial pharmaceutical inspector shall issue a decision on suspension of trading in specific batches of a medicinal product within his area of competence. The provincial pharmaceutical inspector shall immediately notify his decision to the Main Pharmaceutical Inspector. 2. Decision on suspension of trading in the product throughout the country shall be made by the Main Pharmaceutical Inspector. 3. In case of a grounded suspicion that a medical device fails to meet the requirements that apply to it, the provincial pharmaceutical inspector shall immediately notify same to the Office President and the Main Pharmaceutical Inspector and ensure that the medical device is no longer placed on the market or put into service on terms defined for medicinal products."

Article 90.
The Act of 30 August 2002 on conformity assessment system (Journal of Laws 2002, No. 166, item 1360, as amended4)), in Article 1, paragraph 2 shall be amended to read: "2. The provisions of this Act shall not apply to devices being medical devices as defined in the Act of 20 April 2004 on medical devices (Journal of Laws 2004, No. 93, item 896)."

Article 91.
The Act of 23 January 2003 on general insurance in the National Health Fund (Journal of Laws 2003, No. 45, item 391, as amended5)) shall be amended as follows: 1) in Article 5, subparagraph 29 shall be amended to read:
"29) medical devices – it shall mean devices referred to in the provisions on medical devices."
2) in Article 57:
a) paragraphs 1 to 3 shall be amended to read: "1. Basic, supplementing, and prescription medicines, as well as medical devices shall be released to an insured person on the basis of a prescription in generally available pharmacies and company pharmacies subordinated to the Minister of National defence or the minister competent for internal affairs: 1) for lump-sum payment – in case of basic and prescription medicines and medical devices
2) for payment of 30% or 50% of the medicine price – in case of supplementing medicines and medical devices. 2. The lump-sum or partial payment shall apply to single packaging of a medicine or medical device specified in the listings referred to in paragraph 5, subparagraph 1. 3. The lump-sum payment shall not exceed 0,5% of the minimum salary in case of basic medicines and medical devices and 1,5% in case of prescription medicines and medical devices." b) paragraphs 5 and 6 shall be amended to read: "5. The minister competent for health, having consulted the Fund President, the Supreme Medical Council, and the Supreme Council of Pharmacists, shall, by regulation, determine: 1) the listing of basic and supplementing medicines and medical devices
2) the amount of lump-sum payment for basic and prescription medicines and medical devices
3) the amount of payment for supplementing medicines and medical devices
4) the listing of medicines which may be treated as pharmaceutical raw materials for purposes of preparing prescription medicines
5) the quantity of a prescription medicine to which the lump-sum payment applies and the method of calculating the cost of preparing a prescription medicine
- taking into consideration, in particular, the need to ensure social health protection, availability of medicines and safety of their use, as well as payment capabilities of the Fund. 6. The listings of basic and supplementing medicines and medical devices referred to in paragraph 5, subparagraph 1 shall be updated at least twice a year." 3) in Article 62:
a) paragraph 1 shall be amended to read: "1. Entities responsible or manufacturer, hereinafter referred to as "the applicant", may file applications to the minister competent for health for putting these medicines on the listings referred to in Article 57, paragraph 5, subparagraph 1, and Article 58, paragraph 2, subparagraph 2." b) after paragraph 1, paragraph 1a shall be added, reading: "1a. Manufacturer, authorised representative, distributor or importer of medical devices, hereinafter referred to as "the applicant", may file applications to the minister competent for health for putting these devices on the listings referred to in Article 57, paragraph 5, subparagraph 1, and Article 58, paragraph 2, subparagraph 2."

Article 92.
Quality certificates, registration certificates, admission to trade certificates, admission to use certificates, and positive opinions of medical devices issued before 1 October 2002 shall remain in force for the period specified therein, not longer, however, than until 31 December 2005.

Article 93.
Devices stored as State reserves within the meaning of the Act of 30 May 1996 on State reserves and compulsory fuel stocks (Journal of Laws 2003 No. 24, item 197 and 2004, No. 42, item 386) may be put into service, even if they do not meet the requirements stipulated in this Act, on terms specified in Article 92.

Article 94.
Medical devices, whose model has been approved by Directive 76/764/EEC of 27 July 1976 on the approximation of the laws of the Member States on clinical mercury-in-glass, maximum reading thermometers, may be placed on the market and put into service until 30 June September 2004.

Article 95.
Medical devices manufactured from animal tissues or from products derived from such tissues, which do not have a CE design examination certificate or CE type examination certificate, may be placed on the market and put into service until 30 September 2004.

Article 96.
In vitro diagnostic medical devices which do not meet the essential requirements and do not bear the CE-marking may be put into service until 7 December 2005.

Article 97.
1. Medical devices containing stable blood derivatives which do not meet the requirements laid down herein may be placed on the market until 13 December 2005. 2. Medical devices referred to in paragraph 1 may be put into service until 13 December 2007.

Article 98.
1. The Register of Manufacturers and Medical Devices kept in accordance with the regulations previously in force shall become the Register of medical devices and entities responsible for their placing on the market and putting into service. 2. Whoever is obliged under this Act to notify a device to the Register of medical devices and entities responsible for their placing on the market and putting into service and has had this device entered into the Register of Manufacturers and Medical Devices in accordance with the regulations previously in force, shall supplement such notification by 30 June 2005. 3. No fee shall be collected for the notification referred to in paragraph 2.

Article 99.
If a device placed on the market prior to the date when this Act comes into force fails to meet the essential requirements referred to in Chapter 4, but bears a CE-marking under separate regulations, its manufacturer shall specify such other regulations in the documentation accompanying the device.

Article 100.
CE marking shall not be affixed on medical devices failing to meet the requirements specified in this Act and intended by the manufacturer for export outside the territory of the European Union Member States or the European Free Trade Agreement (EFT a) Member States, being parties to the European Economic Area Agreement. Such devices shall be marked so as to make them distinguishable from devices intended for markets of the European Union Member States and the European Free Trade Agreement (EFT a) Member States, being parties to the European Economic Area Agreement.

Article 101.
Any cases instituted but not completed prior to the date when this Act comes into force shall be governed by the regulations previously in force.
Article 102.

The previous implementing provisions issued on the basis of the Article 12, paragraph 2, Article 27, paragraph 4, and Article 30, paragraph 2 of the Act of 27 July 2001 on medical devices (Journal of Laws 2001, No. 126, item 1380, and 2002, No. 152, item 1264) shall remain in force until the issue of new implementing provisions on the basis of Articles 19 to 21, 58 and 68, in the wording given in this Act, not longer, however, than until 31 December 2004.

Article 103.
Whenever in the provisions of law in force there is a reference to medical equipment, medical apparatuses, medical materials or medical devices, it shall mean medical devices as defined in this Act.

Article 104.
The Act of 27 July 2001 on medical devices (Journal of Laws 2001, No. 126, item 1380 and 2002 No. 152, item 1264) and Articles 4, 4a, 4b, and 24a of the Act of 6 September 2001 – Provisions introducing the Pharmaceutical Law Act, the Act on medical devices, and the Act on the Office for Registration of Medicinal Products, Medical Devices, and Biocides (Journal of Laws 2001, No. 126, item 1382 and No. 154, item 1801
and 2002
No. 32, item 300 and No. 152, item 1266, and 2004, No. 10, item 77) shall lose their force.

Article 105.
Until the establishment of the European Databases, a manufacturer placing an in vitro diagnostic medical device on the market in the territory of the Republic of Poland shall notify this placing on the market to the Office President.

Article 106.
This Act shall come into force as of the date when the Republic of Poland becomes the European Union Member State.
1)The provisions of this Act implement the provisions of the following Directives: - Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices
- Council Directive 93/42/EEC of 14 June 1992 concerning medical devices
- Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices
- Commission Directive 2003/12/EC of 3 February 2003 on the reclassification of breast implants in the framework of Directive 93/42/EEC concerning medical devices
- Commission Directive 2003/32/EC of 23 April 2003 introducing detailed specifications as regards the requirements laid down in Council Directive 93/42/EEC with respect to medical devices manufactured utilising tissues of animal origin. 2) Amendments to the consolidated text of this Act were announced in Journal of Laws 2002, No. 76, item 691, No. 152, item 1266, No. 153, item 1271
and 2003, No. 90, item 845. 3) Amendments to this Act were announced in Journal of Laws 2001, No. 154, item 1800
2002
No. 155, item 1286, No. 166, item 1360
2003, No. 170, item 1652
and 2004, No. 49, item 465. 4) Amendments to this Act were announced in Journal of Laws 2003, No. 80, item 718, No. 130, item 1188, No. 170, item 1652, and No. 229, item 2275
and 2004, No. 70, item 631 and No. 92, item 881. 5) Amendments to this Act were announced in Journal of Laws 2003, No. 73, item 660, No. 96, item 874, No. 122, item 1143, No. 128, item

1176, No. 135, item 1268, No. 166, item 1609, No. 190, item 1864, No. 202, item 1956, No. 210, item 2037, No. 223, item 2217 and No. 228, item 2255
and 2004, No. 5, item 37, No. 19, item 177, No. 64, item 593 and No. 93, item 892.