ACT
of 20 May 2010
on medical devices1,2

Chapter 1
General provisions

Article 1.

The Act specifies:

1) The rules governing the placing on the market and putting into service of:

1 The Act implements the following legal acts:

a) Medical devices, accessories for medical devices;
b) In vitro diagnostic medical devices, accessories of in vitro diagnostic medical devices;
c) Active implantable medical devices;
d) Systems and procedure packs consisting of medical devices – hereinafter referred to as “devices;”

2) Rules governing clinical evaluation of medical devices, accessories of medical devices and active implantable medical devices;
3) Rules governing the submission of in vitro diagnostic medical devices and accessories of in vitro diagnostic medical devices for performance evaluation;
4) Rules governing the supervision of:
   a) Manufacturing the devices, placing them on the market and putting them into service;
   b) The devices placed on the market and put into service;
   c) Medical incidents and measures concerning the safety of the devices;
5) Rules of submitting reports and notifications concerning the devices and manufacturers, authorised representatives, importers and distributors of the devices;
6) Rules and manner of authorising the bodies applying for authorisation, notifying the bodies applying for notification with regard to the devices and supervising the notified bodies, authorised by the minister competent for health;
7) Classification of medical devices and accessories of medical devices;
8) Conformity assessment procedure for the devices;
9) Essential requirements for the devices;
10) Obligations of importers and distributors of the devices;
11) Rules governing the use and maintenance of the devices.

**Article 2.**

1. The terms used in the Act shall have the following meaning:

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

2) Authorised representative – any entity having the place of residence or the registered office in a Member State which is designated by the manufacturer to act on his/her behalf and may be addressed by authorities and bodies of the Member States instead of the manufacturer with regard to the latter's obligations under this Act;

3) Clinical investigator – person responsible for conducting clinical investigations and for the health of subjects connected with participation in the clinical investigation;

4) Clinical investigation – designed and planned systematic investigation in human subjects intended to verify safety or the effects of a certain medicinal product, accessories of a medicinal product or an active implantable medical device;

5) Usage error – action of the person using the device or failure to perform an action which produces a result that is different than that assumed by the manufacturer or expected by the person;

6) Total replacement – subjecting the marketed device to all the following treatments:
a) Disassembly of components or sub-assemblies of the device, Verification if the components or sub-assemblies of the device are fit for further use,

c) Replacement or regeneration of the components or sub-assemblies of the device which are not fit for further use,

d) Assembly of the regenerated original or replaced components or sub-assemblies of the device,

e) Verifying if the assembled device meets the original or modified criteria of approval,

f) Marking the device as “totally replaced”
   - In order to re-market it without changing its assumed use under the name of the entity responsible for performing the said actions;

7) Certification – an activity of a notified body proving that the conformity assessment procedure has been performed and confirming that the appropriately identified device, its design, type, manufacturing, sterilisation or control and final examinations are in conformity with essential requirements, completed with the issue of a certificate of conformity;

8) Certificate of conformity – a document issued by a body notified in the area of devices proving that the conformity assessment procedure has been performed and confirming that the appropriately identified device, its design, type, manufacturing, sterilisation or control and final examinations are in conformity with essential requirements;

9) Serious adverse event – a medical event due to which a subject:

a) Died,

b) Suffered serious deterioration of health,
   - Suffered a life-threatening disease or trauma,
   - Suffered permanent disability of bodily structure or function,
   - Required hospitalisation or extension of hospitalisation,
   - Required medical intervention to prevent permanent disability of bodily structure or function,

c) Suffered the death of foetus, threat to the life of the foetus, a congenital defect or labour-related damage;

10) Clinical data – information concerning safety of effect of a medical device, accessories of a medical device or an active implantable medical device obtained as a result of their use, derived from:

a) Clinical investigation of a medical device, accessories of a medical device or an active implantable medical device,

b) Clinical investigation of a medical device or other investigations whose results have been published in scientific literature concerning a similar medical device, accessories of a medical device or an active implantable medical device, which can be proven as equivalent to the given medical device, accessories of a medical device or an active implantable medical device,

c) Published or unpublished accounts of other experiments concerning the use of the given medical device, accessories of a medical device or an active implantable medical device or a similar medical device, accessories of a medical device or an active implantable medical device which can be proven as equivalent to the given medical device, accessories of a medical device or an active implantable medical device;

11) Declaration of conformity – a declaration of the manufacturer or his/her authorised representative, under their exclusive responsibility, that the device fulfils the essential requirements;

12) Distributor – any entity having the place of residence or the registered office in a Member State which delivers or makes available the device after it has been placed on the market; the distributor is also any service provider who imports a device intended to provide medical services by the provider to the territory of the Republic of Poland from the territory of another Member State;
13) Importer – any entity having the place of residence or the registered office in a Member State which places on the market a device from outside the territory of the Member States; the importer is also the service provider which imports a device intended to provide medical services by the provider to the territory of the Republic of Poland from outside the territory of the Member States;

14) Medical incident:
   a) Any malfunction, failure or deterioration in the characteristics 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, in the case of an in vitro diagnostic medical device or an accessory of an in vitro diagnostic medical device, also indirectly of another person or to a serious deterioration in his/her state of health, or
   b) Any technical or medical reason in relation to the characteristics or performance of a device which might lead to or might have led to the death of a patient or user or, in the case of an in vitro diagnostic medical device or an accessory of an in vitro diagnostic medical device, also indirectly of another person or to a serious deterioration in his/her state of health, leading for these reasons to undertaking external corrective measures for safety by the manufacturer;

15) Invasive medical device – a medical device or an accessory of a medical device which is intended to be totally or partially introduced into the human body through a natural orifice or through the surface;

16) Notified body – a body which was granted an identification number assigned by the European Commission and was included in a list of the notified bodies published in the Official Journal of the European Union;

17) Calibrator – a substance, material or article intended by the manufacturer to be used for the purpose of establishing the measuring relations of an in vitro diagnostic medical device;

18) Control material – a substance, material or article intended by the manufacturer to be used for the purpose of verifying the operation characteristics of an in vitro diagnostic medical device;

19) Incorrect use – action of the person using the device or device user or failure to perform an action which produces a result that exceeds the risk-steering measures of the manufacturer, understood as technically feasible and economically viable measures the manufacturer may apply to reduce the severity of potential damage or to mitigate the risk of a damage;

20) Safety note – safety communication sent by the manufacturer or an authorised representative to recipients or users of marketed devices in relation to internal corrective measures concerning safety;

21) Body orifice – a natural orifice of the body, external surface of the eyeball or a permanent artificial orifice, in particular an artificial stoma;

22) Member State – a Member State of the European Union or a Member State of the European Free Trade Area (EFTA – party to the Agreement on the European Economic Area, or Swiss Confederation;

23) Serious deterioration of health:
   a) A life-threatening disease,
   b) Permanent weakening of body functions or a permanent damage to body structure,
   c) Condition which requires medical intervention to prevent the conditions under (a) and (b), or
   d) Death of a foetus, threat to the life of the foetus, a congenital defect or labour-related damage – also including those caused indirectly by erroneous results of diagnostic tests produced by devices used in accordance with instructions of use provided by the manufacturer;

24) Serious threat to public health – high risk of death or a serious deterioration of health of many people which requires taking immediate actions aimed at minimising the risk;
25) Reagent product – a product in which reagents are contained in or placed on the carrier, in particular test strips and test plates;
26) Professional user – a person who is a service provider or a service provider’s employee, having the knowledge or professional experience necessary to use the device in accordance with its purpose;
27) Intended use – the use for which the device is intended in accordance with the data provided by the manufacturer in the form of markings, instructions of use or promotional materials;
28) Sponsor – any entity responsible for initiating and conducting a clinical investigation having the place of residence or the registered office in a Member State or acting solely through the agency of its legal representative having the place of residence or the registered office in a Member State;
29) Service provider – a service provider within the meaning of the Act of 27 August 2004 on health care services financed from public funds (Dz. U. of 2008, No 164, item 1027, as amended);
30) Subject – a person participating in a clinical investigation who uses the analysed device or a control comparative method or who is diagnosed using the analysed device or the control comparative method;
31) Placing on the market – the first making available in return for payment or free of charge of a new or fully refurbished device other than a device intended for clinical investigation and a device for assessment of performance, with a view to distribution or use on the Member State market;
32) Putting into service – the first making available of a device ready for use to the user on the Member State market with a view to use it for its intended purpose;
33) Accessory of a medical device – an article which is not a medical device but is specifically intended by the manufacturer to be used with the medical device in order to allow using it in accordance with its intended use;
34) Accessory of an in vitro diagnostic medical device – an article which is not an in vitro diagnostic medical device but is specifically intended by the manufacturer to be used with the in vitro diagnostic medical device in order to allow using it in accordance with its intended use, with the exception of a medical device which is an invasive instrument to collect samples or an instrument applied directly to human body to collect samples;
35) Device for a clinical investigation – a medical device, an accessory of a medical device or an active implantable medical device intended for use during clinical investigations;
36) Device for performance assessment – an in vitro diagnostic medical device or accessory of an in vitro diagnostic medical device intended for tests evaluating its operation outside the enterprise of the manufacturer, in venues where in vitro diagnostic tests are performed;
37) Device for self-control – an in vitro diagnostic device intended by the manufacturer to be used at home by persons who are not professional users and who will refer the test result to the person under examination;
38) Medical device – any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic or therapeutic purposes and 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 of or compensation for an injury or handicap,

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

d) Control of conception
- 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;

39) In vitro diagnostic medical device:

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

b) Specimen receptacles specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination,

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

40) Implantable medical device – any medical 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 and any medical 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;

41) New device – an in vitro diagnostic medical device which, in respect of the given analyse or another parameter, has not been constantly available within the last three years in the territory of a Member State or in the case of which the procedure applied is based on an analytic procedure which has not been constantly used within the last three years in the territory of a Member State in respect of the given analyse or another parameter;

Custom-made device – a medical device, an accessory of a medical device or an active implantable medical device manufactured in accordance with a written prescription of a physician or, in the case of a medical device and an accessory of a medical device, of another person based on his/her professional qualifications, stating the characteristics of the design on the responsibility of the physician or the said person, intended for exclusive use in a specified patient, which are not mass-produced and require adjustment to specific requirements of a physician or other professional user;

43) Device made by the user – a device made and used by the service provider at the place where it was made, which was not transferred to be used by a different person or entity and which is not a custom-made device, an in vitro diagnostic medical device or an accessory of an in vitro diagnostic medical device;

44) Device with a measuring function – a medical device or an accessory of a medical device which jointly meet the following criteria:

a) They are intended by the manufacturer to measure the quantitative physiological or anatomical parameter or to measure the quantity or qualitative characteristics of energy or substances provided to or collected from human body,

b) The measurement result is expressed in a legal measurement unit or compared to at least one reference point indicating value expressed in a legal measurement unit,
c) Their intended use implies precision, expressly declared or implied, the inconsistency with which may result in side effects significant to the health or safety of the patient;

45) Manufacturer:

a) The entity with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his/her own name, regardless of whether these operations are carried out by that entity itself or on its behalf by a third party;

b) Any entity that assembles, packages, processes, fully refurbishes or labels a ready-made product or assigns to it its intended purpose with a view to its being placed on the market under its own name, excluding the entity that assembles or adapts devices already on the market to their intended purpose for an individual patient;

46) External corrective measures concerning safety – measures taken by the manufacturer with a view to minimising the risk of death or a serious deterioration of health connected with the device placed on the market, which covers returning the device to the manufacturer, modifying, replacement or destruction of the device, modernisation by the purchaser to introduce the modification, structure change or recommendation on the use of the device defined by the manufacturer.

2. The provisions of the Act concerning medical devices shall apply to accessories of medical devices.


**Article 3.**

1. The provisions of the Act shall not apply to the following:

1) Medicinal products within the meaning of Article 2(32) of the Act of 6 September 2001 – Pharmaceutical Law (Dz. U. of 2008, No 45, item 271, as amended⁴);

2) Cosmetics within the meaning of Article 2(1) of the Act of 30 March 2001 on cosmetics (Dz. U. No 42, item 473, as amended⁵);

3) Human blood, blood products within the meaning of Article 2(31) of the Act of 6 September 2001 – Pharmaceutical Law, human plasma, human blood cells and medical devices and active implantable medical devices which, at the time of placing on the market, contain the above blood products, plasma or cells, without prejudice to Article 4(1);

4) Transplants, tissues and human cells and medical devices and active implantable medical devices which contain the above tissues or cells or derived from such tissues or cells, without prejudice to Article 4(1);

5) Transplants, tissues and animal cells and medical devices and active implantable medical devices which contain the above tissues or cells, with the exception of medical devices or active implantable medical devices manufactured using animal tissues deprived of the ability to live or products incapable of living derived from animal tissues;

6) Devices intended for the country’s defences and security set forth in regulations issued pursuant to the Act of 17 November 2006 on the conformity assessment system for products intended for the State's defences and security (Dz. U. No 235, item 1700);

7) In vitro diagnostic medical devices manufactured by the service provider’s laboratory and used at the venue of manufacturing, unless they were provided to another entity, yet the essential requirements provided for in the Act apply in the area of safety of the products, without prejudice to Article 4(7);

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⁴ Amendments to the consolidated text of the said Act have been announced in Dz. U. of 2008 No 227, item 1505 and No 234, item 1570, of 2009 No 18, item 97, No 31, item 206, No 92, item 753, No 95, item 788 and No 98, item 817 and of 2010 No 78, item 513.

⁵ Amendments to the said Act have been announced in Dz. U. of 2003 No 73, item 659, No 189, item 1852 and No 208, item 2019, of 2004 No 213, item 2158 and of 2009 No 18, item 97, No 20, item 106 and No 91, item 740.
8) Reference materials with international certificates and materials used for external evaluation of the quality of work of medical diagnostic laboratories, if they are not calibrators or control materials;

9) Aids for the disabled intended to relieve or compensate the effects of their disability, if there is no direct relationship between the function of the aids and the disabled, e.g. sound signals in signalling systems at pedestrian crossings, elevators and ramps for the disabled, special equipment in public toilets for the disabled.

2. The provisions of the Act shall not apply to components and half-finished products intended by their manufacturers to produce goods, with the exception of components and half-finished products intended by their manufacturers specifically to produce custom-made goods to which the provisions of the Act concerning a medical device, accessories of medical devices and active implantable medical device apply accordingly.

Article 4.

1. The provisions of the Act apply where a medical device or an active implantable medical device incorporates, as an integral part, a substance which, if used separately, may be considered to be a blood product and which is liable to act upon the body with action ancillary to that of the medical device or an active implantable medical device.

2. The provisions of the Act apply where a medical device or an active implantable medical device incorporates, as its integral part, a substance which, if used separately, may be considered to be a medicinal product and which is liable to act upon the body with action ancillary to that of the medical device or an active implantable medical device.

3. The provisions of the Act apply where a medical device is intended to administer a medicinal product. However, when a medical device is placed on the market in a way that it forms an inseparable single product with a medicinal product intended to be used solely together and which is not fit for reuse, the product shall be subject to the provisions of the Act of 6 September 2001 – Pharmaceutical Law, while relevant essential requirements set forth in this Act shall apply to the extent to which they concern the features of the given medical device connected with its safety and operation.

4. The provisions of the Act apply to spare and replacement parts intended to replace parts and elements of the device if the spare and replacement parts have not been covered by the device’s conformity assessment and change the features or operation of the device as compared to its approved conformity assessment.

5. In case an active implantable medical device is intended to administer a medicinal product, the provisions of this Act shall apply to the active implantable medical device and the provisions of the Act of 6 September 2001 – Pharmaceutical Law shall apply to the medicinal product.

6. To determine whether the given product is a medical device or a medicinal products, its manner of operation shall be the decisive factor. An in vitro diagnostic device manufactured by a medical diagnostic laboratory or another entity which uses it to render publicly available medical diagnostic services without placing it on the market shall be subject to the Act and must be marked with the EC mark following an appropriate conformity assessment procedure.

Article 5.

1. As concerns placing on the market and putting into service, the provisions of the Act shall apply to devices in the condition in which they are supplied to users.

2. The provisions of the Act shall also apply to devices which are not supplied to users in a ready-to-use condition, but which may be processed, prepared, sterilised, configured, installed, assembled or fitted by the user or the service provider using the device prior to its use.
3. The user or the service provider using the device who perform the actions referred to in Paragraph 2 are not manufacturers and the requirements for the process of manufacturing, sterilisation and compiling a system or a procedure pack shall not apply to these actions.

Chapter 2
Placing devices on the market, putting them into service and subjecting to performance assessment

Article 6.
It is forbidden to place on the market, put into service, subject to performance assessment, distribute, supply, make available, install, launch and use devices which constitute a threat to the safety, life or health of patients, users or other persons that exceeds the acceptable risk determined on the basis of the current knowledge, when they have been delivered, installed and maintained correctly and used in accordance with their intended purpose.

Article 7.
It is forbidden to place on the market, put into service, distribute, supply, make available, install, launch and use devices after their expiry date or devices whose time of use or the number of safe uses set by the manufacturer was exceeded.

Article 8.
1. It is forbidden to place on the market, put into service, distribute, supply and make available devices whose names, markings or instructions of use may be misleading as to the properties and operation of the device by:
   1) Attributing properties, functions and operations to a device which are non-existent;
   2) Making a false impression that treatment or diagnosis with the device would surely be successful or failure to inform of the expected risk connected with using the device in accordance with its intended use or for a period longer than intended;Suggesting use or device properties other than those declared during the conformity assessment.
2. Promotional materials, presentations and information on devices may not be misleading as specified in Paragraph 1.

Article 9.
In the case of in vitro diagnostic medical devices, disposal, collection and use of tissues, cells and substances of human origin should comply with ethical rules concerning protection of human rights and dignity of a human being.

Article 10.
1. It is forbidden to place devices on the market whose conformity certificate expired, were withdrawn or suspended.
2. It is forbidden to supply and make available in vitro diagnostic medical devices other than the devices referred to in Article 2(1)(39) (b) and (c) or self-control devices to persons who are not professional users, with the purpose of unassisted use.Article 11.
1. The devices placed on the market and put into service shall bear the CE marking.
2. Custom-made devices, devices intended for clinical investigations, devices for performance assessment, devices made by the user, as well as the systems and procedure packs referred to in Article 30(1) and (4) shall not bear the CE marking.
3. Custom-made devices which are active implantable medical devices or class IIa, IIb and III medical devices referred to in Article 20(1) placed on the market and put into service shall be accompanied by a declaration of the manufacturer or authorised representative issued following the completion of a conformity assessment procedure relevant for the device to confirm that the device meets the relevant essential requirements or to state which essential requirements were not met and why. The declaration shall be made available to patients for whom the device is intended, identified by name, acronym or numerical code.

4. The device is affixed with the CE marking following the completion of the relevant conformity assessment procedures, certifying that the device satisfies the applicable essential requirements.

5. If separate provisions also impose the obligation to affix the CE marking to the device, the mark is affixed when the device also meets the requirements provided for in the provisions.

6. The CE marking must appear in a visible, legible and indelible form on the instructions for use and on sales packaging and on:
   1) Packaging ensuring sterility of an active implantable medical device;
   2) An in vitro diagnostic medical device, if possible;
   3) A medical device or its packaging ensuring sterility, if possible.

7. If the conformity assessment has been carried out with the participation of a notified body, the identification number of that body shall be affixed next to the CE marking.

8. It is prohibited to affix marks or inscriptions which are likely to mislead with regard to the CE marking or the number of the notified body, or which reduce the visibility or legibility of the CE marking.

9. The minister competent for health shall specify by ordinance, the model CE marking, considering the need to standardise it for all devices.

Article 12.

The manufacturer without the place of residence or the registered office in a Member State, who, under his/her own name, places the device on the market shall appoint one authorised representative for the device.

Article 13.

1. The manufacturer of the device is responsible for the device, carrying out the conformity assessment of the device before placing it on the market and for placing the device on the market. If the manufacturer does not have place of residence or the registered office in a Member State, the responsibility shall be on the authorised representative for the device. If the manufacturer did not appoint the authorised representative or if the device is not placed on the market under the responsibility of the manufacturer or the authorised representative, the responsibility shall be on the entity that placed the device on the market.

2. The name and address of the manufacturer shall be provided within the device marking and in its instructions of use and the name and address of the authorised representative shall be given within the device marking or in its instructions of use.

3. The manufacturer having the place of residence or the registered office on the territory of the Republic of Poland shall keep the list of all service providers and distributors to whom he/she had delivered the devices, for the period for which he/she envisaged the device to be used, and shall make the list available during inspection referred to in Article 69(1)(2) and immediately upon request of the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, hereinafter referred to as “President of the Office.”

Article 14.
1. Devices intended for use in the territory of the Republic of Poland shall have markings and instructions for use in Polish or expressed with harmonised symbols or identifiable codes.

2. Devices intended for use in the territory of the Republic of Poland and delivered to professional users may have markings or instructions for use in English, except for the information for patients which shall be given in Polish or expressed with harmonised symbols or identifiable codes.

3. If the devices have markings in Polish, also the instructions for use shall be in Polish or expressed with harmonised symbols or identifiable codes.

**Article 15.**

1. The President of the Office may, by administrative decision, allow to place on the market or put into service in the territory of the Republic of Poland a device which is necessary to achieve necessary prevention, diagnostic or therapeutic objectives, and for which conformity assessment procedures confirming that the device meets the applicable essential requirements have not been carried out.

2. The decision referred to in Paragraph 1 shall be issued upon request of the service provider, consultant, referred to in the Act of 6 July 2008 on health care consultants (Dz. U. of 2009, No 52, item 419 and No 76, item 641), the President of the Agency for Health Technology Assessment or the President of the National Health Fund, justified with the necessity to save the life or health of a patient or to protect public health.

**Article 16.**

A device incompliant with the requirements specified in the Act may be presented during fairs, exhibitions, demonstrations, presentations and scientific and technical symposia, provided that the device is not used for taking or analysing samples taken from participants of such events and that the device bears the information stating that it cannot be placed on the market and put into service until it meets the requirements specified in the Act.

**Chapter 3 Obligations of importers and distributors**

**Article 17.**

1. The importer and the distributor shall act with due diligence to ensure safety of devices, in particular by not supplying and not making available the devices about which they know, or should know due to the information and professional experience they have, that they do not comply with the requirements specified in the Act.

2. Before placing the device on the market the importer shall verify whether:
   1) The manufacturer or the authorised representative have conducted the appropriate device conformity assessment procedure;
   2) The manufacturer has appointed an authorised representative for the device;
   3) The device bears the CE marking and the identification number of the notified body which participated in conformity assessment, if it is a device referred to in Article 29(5);
   4) The information provided by the manufacturer complies with the essential requirements.

3. The importer and the distributor shall verify whether the devices they place on the market, put into service, deliver or make available are properly labelled and are accompanied by appropriate instructions for use.

4. The importer having the place of residence or the registered office on the territory of the Republic of Poland shall hold and keep at the disposal of the President of the Office, for at least
5 years from the day of placing the device on the market, a copy of the declaration of conformity, of the statement referred to in Article 30(1) or of the statement referred to in Article 30(4), as well as copies of certificates of conformity, if the device placed on the market is a device referred to in Article 29(5).

5. Upon customs clearance of the device, the importer shall provide copies of the declaration of conformity, of certificates of conformity, as well as of the statement referred to in Article 11(3) and of the statement referred to in Article 30(1), or of the statement referred to in Article 30(4).

Article 18.

1. The importer and the distributor having the place of residence or the registered office on the territory of the Republic of Poland shall cooperate in their activity with the President of the Office, the manufacturer, the authorised representative or the entity authorised by the manufacturer to act on his/her behalf in cases involving medical incident and in cases concerning product safety - in order to avoid or eliminate the risk created by the devices they place on the market, put into service, deliver or make available.

2. The importer and the distributor referred to in Paragraph 1, who learned that the device placed by them on the market may be dangerous, shall promptly notify the President of the Office about the fact.

3. The importer and the distributor referred to in Paragraph 1 shall participate in the activities concerning the safety of devices they place on the market, put into service, deliver or make available, and in particular they shall:

1) Collect information from users and patients about the threats caused by the devices and forward such information promptly to the manufacturer or the authorised representative and to the President of the Office;

2) Keep for a period of at least 5 years from the day of delivery of the last device, and promptly provide upon request of the President of the Office, the documentation necessary to determine the origin and unambiguous identification of the devices;

3) Keep the list of all service providers and distributors to whom they delivered the devices for the period, specified by the manufacturer, when the device may be used, and make it available during the control referred to in Article 69(1)(2) as well as immediately upon request of the President of the Office;

4) Carry out the activities concerning safety specified by the manufacturer.

Article 19.

The importer and the distributor shall ensure that the storage and transport conditions of the device, within the period when they are responsible for the device, do not adversely affect its compliance with the requirements specified in the Act.

Chapter 4

Classification of medical devices and qualification of in vitro diagnostic medical devices, as well as essential requirements and conformity assessment procedures

Article 20.

1. Medical devices shall be classified into Classes I, IIa, IIb or III, taking into account the risk related to their use.

2. The minister competent for health shall specify by ordinance the method of classifying medical devices, taking into account the duration of contact with the body, place of contact,
degree of invasiveness, local and systemic effects, performed function, and applied
technologies.

**Article 21.**

In vitro diagnostic medical devices, which, due to serious consequences of erroneous result of the examination using those devices, require special conformity assessment procedures, shall be classified to:

1) List A, or
2) List B.

**Article 22.**

1. Discrepancies concerning the classification of a medical device or the qualification of an in vitro diagnostic medical device arising between the manufacturer and the notified body authorised by the minister competent for health shall be resolved, by administrative decision, by the President of the Office.

2. In case of incorrect classification of a medical device, or incorrect qualification of an in vitro diagnostic medical device:

   1) Which is placed on the market or put into service on the territory of the Republic of Poland,
   2) Whose manufacturer, authorised representative or importer responsible for placing the device on the market has the place of residence or the registered office on the territory of the Republic of Poland,
   3) In whose conformity assessment a notified body authorised by the minister competent for health took part,

   - The classification or qualification shall be determined by the President of the Office by administrative decision.

**Article 23.**

1. Devices must meet the relevant applicable essential requirements.

2. The minister competent for health shall specify by ordinance:

   1) Essential requirements;
   2) Conformity assessment procedures;
   3) Detailed technical specifications – for medical devices produced using tissues of animal origin;
   4) The list of conformity assessment procedures which can be carried out by the authorised representative;
   5) The fee, referred to in Article 29(9), for medical devices, taking into account the type, classification and intended use of the device, the quality system implemented by the manufacturer, as well as the need to protect life, health and safety of patients, users and third persons; and also while determining the fee, taking into account the type of substance constituting an integral part of the medical device, amount of work and costs incurred by the President of the Office in relation to issuing an opinion.

3. The minister competent for health shall specify by ordinance:

   1) Essential requirements;
   2) Conformity assessment procedures;
   3) The list of conformity assessment procedures which can be carried out by the authorised representative;
   4) The List A and List B referred to in Article 21;
for in vitro diagnostic medical devices, taking into account the type, intended use and risk related to using the devices, in particular the risk resulting from a possible wrong diagnosis, its impact on medical procedures and on the possibility of detecting errors, as well as the quality system implemented by the manufacturer, and the need to protect life, health and safety of patients, users and third persons.

4. The minister competent for health shall specify by ordinance:
   1) Essential requirements;
   2) Conformity assessment procedures;
   3) The list of conformity assessment procedures which can be carried out by the authorised representative;
   4) The amount of fee, referred to in Article 29(9);

- for active implantable medical devices, taking into account the particular risk related to using the devices, as well as the quality system implemented by the manufacturer and the need to protect life, health and safety of patients, users and third persons; and also while determining the fee, taking into account the type of substance constituting an integral part of the active implantable medical device, the amount of work, and the costs incurred by the President of the Office in relation to issuing an opinion.

**Article 24.**

A medical device intended by its manufacturer to be used also as personal protective equipment shall also comply with the essential requirements for health protection and safety, laid down in the regulations on personal protective equipment issued pursuant to Article 9 of the Act of 30 August 2002 on conformity assessment system (Dz.U. of 2004 No 204, item 2087, as amended).

**Article 25.**

In case of a threat, a medical device being at the same time a machine shall meet essential requirements for health protection and safety, issued pursuant to Article 9 of the Act of 30 August 2002 on the conformity assessment system, in the scope in which such essential requirements are more detailed than the essential requirements laid down in the provisions issued pursuant to Article 23 (2).

**Article 26.**

The devices shall be presumed to comply with the essential requirements referred to in Article 23(1) in the scope in which they are in conformity with the relevant national standards adopted pursuant to standards published in the Official Journal of the European Union, C Series, as the standards harmonised with:


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Amendments to the consolidated text of the said Act were published in Dz. U. of 2005 No 64, item 565 and No 267, item 2258, of 2006 No 170, item 1217, No 235, item 1700 and No 249, item 1832 and 1834, of 2007 No 21, item 124 and No 192, item 1381; of 2008 No 157, item 976 and No 227, item 1505; and of 2009 No 18, item 97.

**Article 27.**

Monographs of the European Pharmacopoeia or their translations into Polish included in the Polish Pharmacopoeia shall also be considered harmonised standards with regard to medical devices and active implantable medical devices.

**Article 28.**

1. An in vitro diagnostic medical device shall be presumed to comply with the essential requirements, if it was designed and manufactured in conformity with common technical specifications specified in the Decision of the European Commission.
2. Common technical specifications shall be considered harmonised standards with regard to in vitro diagnostic medical devices.
3. If for duly justified reasons the requirements specified in common technical specifications are not met, the manufacturer shall adopt solutions of a safety level at least equivalent thereto.

**Article 29.**

1. Before placing the device on the market, and before submitting the device for clinical investigation or performance assessment, the manufacturer shall carry out the conformity assessment of the device.
2. The manufacturer may entrust the authorised representative with performing some conformity assessment procedures, specified in the provisions issued pursuant to Article 23(2)(4), Article (3)(3), and Article (4)(3).
3. Before using for the first time an own-made device, the user must carry out the conformity assessment of the device.
4. The conformity assessment shall be carried out by the manufacturer or the authorised representative, on their own or under supervision of the notified body.
5. The conformity assessment of:
   1) Class I medical devices with a measuring function;
   2) Class I medical devices – sterile;
   3) Class IIa medical devices;
   4) Class IIb medical devices;
   5) Class III medical devices;
   6) Active implantable medical devices;
   7) In vitro diagnostic medical devices from List A;
   8) In vitro diagnostic medical devices from List B;
   9) Devices for self-testing;
   - other than custom-made devices, devices intended for clinical investigation, devices for performance assessment and devices made by the user shall be carried out by the manufacturer or by the authorised representative with the participation of the notified body competent for the scope of notification, based on the concluded agreement.
6. While performing the conformity assessment of the device, the manufacturer, the authorised representative and the notified body shall take into account the result of each assessment and verification which were carried out pursuant to the Act at intermediate stages of manufacturing.
7. Under the conformity assessment procedure, the notified body shall obtain an opinion on the quality and safety of the substance, including the opinion on clinical benefits to risk ratio, from:
   1) The authority competent for medicinal products in a Member State or from the European Medicines Agency (EMEA) – where a medical device or an active implantable medical device incorporates, as its integral part, a substance which, if used separately, may be considered to be a medicinal product, and which is liable to act upon the body with action ancillary to that of the device;
   2) The European Medicines Agency (EMEA) – where a medical device or an active implantable medical device incorporates, as its integral part, a substance which, if used separately, may be considered to be a blood product, and which is liable to act upon the body with action ancillary to that of the device.
8. The President of the Office shall be the authority competent to issue the opinion referred to in Paragraph 7(1) on the territory of the Republic of Poland.
9. The issuance of the opinion by the President of the Office shall be subject to a fee constituting revenue of the state budget, and which cannot exceed twenty minimum wages determined pursuant to the regulations on the minimum wage.
10. The notified body may require any information or data necessary to issue, restore or extend the validity of the certificate of conformity.

Article 30.

1. An entity who puts devices bearing the CE marking together, within their intended purpose and within the limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack, shall draw up a declaration by which he/she states that:
   1) Mutual compatibility of the devices has been verified in accordance with the manufacturers’ instructions, and the operations provided for in these instructions have been carried out;
   2) System or procedure pack has been packed, and relevant information has been supplied to users, including relevant instructions for using medical devices included therein;
   3) Whole activity has been subject to appropriate internal control and inspection procedures.
2. The system or the procedure pack compliant with the requirements specified in Paragraph 1 shall not be subject to the conformity assessment.
3. If the conditions referred to in Paragraph 1 are not met, in particular if the system or procedure pack incorporates a medical device which does not bear a CE marking or if the chosen combination of medical devices is not compatible taking account their original intended use, the system or procedure pack shall be subject to the conformity assessment.
4. An entity that sterilizes the system or procedure pack referred to in Paragraph 1, for the purpose of placing it on the market, or that sterilizes some other CE-marked medical device designed by its manufacturer to be sterilized before use, shall carry out the conformity assessment procedure under the supervision of the notified body competent for the scope of notification, pursuant to the concluded agreement, and shall draw up a declaration stating that sterilization has been carried out in accordance with the manufacturer's instructions. The application of the conformity assessment procedure and the participation of the notified body in the procedure are limited to the aspects relating to ensuring sterility until the sterile packaging is opened or damaged.
5. The medical device referred to in Paragraph 4 shall not be marked with the CE marking again.
6. The system or the procedure pack and the medical device referred to in Paragraphs 1 and 4 shall be accompanied by the information specified in the essential requirements for medical devices, in the part concerning the information supplied by the manufacturer, including, if
justified by the safety of use of the system or the procedure pack, the information supplied by the manufacturers of the devices which have been put together.

Article 31.
The entity having the place of residence or the registered office on the territory of the Republic of Poland shall keep the declarations referred to in Article 30(1) and (4) at the disposal of the President of the Office for a period of 5 years from placing on the market of the last system, procedure pack or sterilized medical device.

Article 32.
1. The manufacturer shall keep the conformity assessment documentation of the device for a period of 5 years from the end of its production.
2. The documentation of the conformity assessment of implantable medical devices and active implantable medical devices shall be kept for 15 years from the day on which their production has ended.
3. If the manufacturer does not have the place of residence or the registered office in a Member State, the obligations specified in Paragraphs 1 and 2 shall be performed by the authorised representative.

Chapter 5
Rules and procedure of authorising the bodies applying for authorisation, as well as of notifying and supervising the notified bodies with regard to the devices, authorised by the minister competent for health

Article 33.
1. The body applying for notification for devices must obtain an authorisation.
2. Granting authorisation as well as changing its scope shall be performed by the minister competent for health, by way of administrative decision, issued upon request of a given body, if the body meets the following criteria:
   It has sufficient personnel with adequate knowledge and experience to evaluate the functionality and performance of the devices, as well as knowledge about their conformity assessment procedures;
   The director and personnel participating in conformity assessment and verifications are not manufacturers, authorised representatives, suppliers, designers, service technicians of the devices, or service providers using the assessed devices, and they do not participate in such activities;
   It ensures impartiality of the certification procedure;
   The personnel of the body participating in conformity assessment and verifications is characterised by the highest level of professional diligence and competence, and there are no indications of their lack of impartiality while performing their activities;
   It has capacity to perform, itself or on its responsibility, all certification related tasks;
   It ensures compliance with the regulations on protection of classified information and of other information protected by law;
   It verifies whether its subcontractors meet the criteria laid down in Subparagraphs 1-5, before they are commissioned with conformity assessment or verification on behalf of the body, and it documents the process.
3. The application for authorisation or for a change of the scope of authorisation shall include:
   Name and address of the registered office of the body applying for authorisation or for changing its scope;
Specification of the scope of authorisation applied for or of its change.

4. The body applying for authorisation shall attach to the application, referred to in Paragraph 3, relevant documents confirming that it meets the criteria laid down in Paragraph 2.

5. The notified body shall attach to its application for changing the scope of authorisation, which consists not only in limiting the previous scope, relevant documents confirming that in the scope covered by the change applied for it has the capacity to perform the certification related tasks - on its own or on its responsibility.

6. The minister competent for health, in his/her decision on granting the authorisation or changing its scope shall specify the scope of the body’s authorisation.

7. The minister competent for health shall, by administrative decision, revoke the authorisation of a notified body upon request of that body.

Article 34.

1. The minister competent for health shall, by administrative decision, revoke the authorisation or limit its scope ex officio, if the notified body does not meet the criteria specified in Article 33(2).

2. The scope of authorisation shall be limited in the part where the notified body lost its capacity to perform the tasks specified in the scope of authorisation, as verified by results of the inspection referred to in Article 37.

3. The minister competent for health shall specify the current scope of authorisation of the body in the decision on limiting the scope of authorisation.

Article 35.

1. The minister competent for health shall promptly notify the minister competent for the economy about issuing the decisions referred to in Article 33(2) and (7), and in Article 34(1).

2. The minister competent for the economy shall notify the notified bodies to the European Commission and Member States, providing the scope of notification or the information about revoking the authorisation, in line with the decisions referred to in Article 33(2) and (7), and in Article 34(1).

3. The minister competent for the economy shall publish, as an official announcement in the Official Journal of the Republic of Poland “Monitor Polski”, the information on notified bodies authorised to certify devices by the minister competent for health, as well as on changing the scope of notification and of its revoking.”

Article 36.

1. The body, which obtained authorisation of the minister competent for health or whose scope of authorisation was changed, shall enter into an obligatory liability insurance contract covering damages caused in relation to conducted authorisation activity, and it shall submit such insurance contract to the minister competent for health within 14 days from the day of receiving the authorisation decision.

2. The notified body shall enter into an obligatory liability insurance contract covering damages caused in relation to conducted notification activity, to which Paragraph 1 shall apply accordingly in the case of changing the scope of authorisation.

3. The minister competent for financial institutions, in consultation with the minister competent for health, having obtained an opinion of the Polish Chamber of Insurance, shall specify, by ordinance, the date on which the insurance obligation occurs and the minimum guarantee amount of insurance, taking into account the specificity of the activity of the notified body in terms of devices, the scope of its notification, the specificity of the activity of the body which received authorisation of the minister competent for health and the scope of its authorisation.
Article 37.

1. The minister competent for health shall supervise the notified bodies and their activities referred to in Article 38, and shall control whether the notified bodies and the bodies applying for authorisation meet the criteria referred to in Article 33(2).

2. The control referred to in Paragraph 1 shall be conducted on the basis of a written authorisation issued by the minister competent for health which shall include:
   1) Surname and name and the number of ID document of person performing the control;
   2) Name of the controlled body;
   3) Date of control, specification of its scope and planned duration.

3. Persons performing the control shall have the right:
   1) To enter the land, buildings and premises of the controlled body during its business days and working hours;
   2) To examine the documentation and to demand information and explanations concerning the scope of notification or the scope of authorisation applied for;
   3) To demand the translation of the specified documentation into Polish.

4. Control activities shall be carried out in the presence of an authorised representative of the body undergoing control.

5. The protocol shall be drawn up from the performed control, and it shall be submitted for signature to the authorised representative of the controlled body.

6. The protocol from control of the notified body may include follow-up recommendations.

7. Within 14 days from receiving the protocol, the controlled body may submit its objections to the protocols, along with their justification.

8. The minister competent for health shall examine the objections within 30 days from receiving them and shall take a stand on the matter which will be final and which will be delivered to the controlled body along with its justification.

9. The notified body shall implement the follow-up recommendations; otherwise the scope of authorisation shall be reduced or the authorisation shall be revoked.

10. The minister competent for health care shall specify by ordinance:
   1) The method of meeting the specific requirements by the bodies applying for authorisation for notification of devices;
   2) The procedure for verifying the conditions and procedures of the functioning of notified bodies authorised by the minister competent for health;
   3) The method of exercising supervision over notified bodies authorised by the minister competent for health;
   4) The detailed scope and procedure for controlling bodies applying for authorisation and notified bodies;
   - Taking into account the need to ensure the harmonised functioning of notified bodies, to ensure safety of devices certified by notified bodies authorised by the minister, and to exercise efficient supervision over those bodies.

Article 38.

1. The notified body may certify for notification.

2. The records and correspondence concerning the conformity assessment procedures, in which the notified body participates, shall be drawn up in Polish or in another official language of a Member State approved by the body.

3. The notified body is competent for issuing certificates of conformity and to change, impose restrictions, supplement, suspend, restore validity and withdraw the certificates of conformity it issued.
4. The notified body shall promptly notify the minister competent for health and the President of the Office about the activities referred to in Paragraph 3 and about the refusal to grant a certificate; and at their request it shall also provide additional information relating to the activities.

5. The notified body shall provide the information referred to in Paragraph 4 to another notified body in the scope of devices, at its request.

6. If the manufacturer does not meet the requirements specified in the Act or if the certificate of conformity was issued not in line with the regulations, the notified body shall suspend, withdraw or impose restrictions on issuing certificate of conformity, if the manufacturer fails to implement corrective actions in order to meet the requirements.

7. The minister competent for health shall notify the European Commission and the Member States about the suspension, withdrawal or restriction of the certificate of conformity by the notified body.

8. The notified body shall inform the President of the Office about the activities, referred to in Paragraph 6, which it undertook.

Chapter 6
Clinical evaluation of medical devices or active implantable medical devices

Article 39.

1. The manufacturer or the authorised representative shall perform a clinical evaluation of a medical device or an active implantable medical device in order to confirm their conformity with the essential requirements concerning the characteristics and performance of the evaluated device, and to evaluate the ratio between undesirable side-effects and acceptability of benefits under the normal conditions of use of the evaluated device.

2. Clinical evaluation shall be based on clinical data.

3. Clinical evaluation shall take account of relevant harmonised standards for the medical device or for the active implantable medical device, and it shall follow a defined and methodologically sound procedure based on:

   1) A critical evaluation of currently available relevant scientific literature relating to safety, performance, design characteristics, and intended purpose of the evaluated device, if:
      a) Equivalence of the evaluated device has been demonstrated with the medical device or the active implantable medical device to which the data relates, and
      b) The data demonstrate compliance with the relevant essential requirements for the device;
   2) A critical evaluation of the results of all clinical investigations made;
   3) A critical evaluation of the combined clinical data referred to in Subparagraphs 1 and 2.

4. Clinical evaluation of active implantable medical devices, medical devices and devices in Class III shall be performed on the basis of clinical data from clinical investigations unless it is duly justified to perform the evaluation based on existing clinical data.

5. The minister competent for health shall specify, by ordinance, the detailed requirements for clinical evaluation of medical devices or active implantable medical devices, taking into account the necessity to ensure reliability of clinical evaluation results.

Article 40.

1. In the case of clinical investigation of:

   1) Medical devices, the clinical investigator may be a doctor or another person with professional qualifications necessary to perform a clinical investigation of a given medical device;
2) Active implantable medical devices, the clinical investigator may only be a doctor.

2. The objectives of clinical investigation under normal conditions of use of devices are:
   1) To verify that the characteristics and performance of devices conform to essential requirements; and
   2) To determine any undesirable side-effects and assess whether they pose acceptable risks, taking into account the intended performance of the device and the benefits for the patient.

3. Clinical investigation shall not be medical investigation conducted using a device bearing CE marking or a custom-made device, the conformity assessment of which was performed in line with the relevant conformity assessment procedures, unless the investigation concerns other application of the device than intended by the manufacturer and presented in the conformity assessment.

4. Clinical investigation shall be conducted taking account of the principle that the well-being of subjects shall be superior to the interest of science or society, in particular if:
   1) The foreseeable risk and inconveniences related to clinical investigation have been weighted against anticipated benefits for individual subjects as well as for present and future patients, and the bioethics committee referred to in Article 29 of the Act of 5 December 1996 on the profession of a physician and a dentist (Dz.U. of 2008 No 136, item 857, as amended\(^7\)), hereinafter referred to as the “bioethics committee”, decided that anticipated therapeutic and public health benefits justify the risk; the clinical investigation may be continued only if compliance with the clinical investigation protocol is permanently monitored by the monitoring entity;
   2) The subject or, when this person is not able to give informed consent, his/her legal representative has had the opportunity, in a prior interview with the investigator or a member of the investigating team, to understand the objectives, risks and inconveniences involved in the clinical investigation, and the conditions under which it is to be conducted, and has also been informed of the right to withdraw from the clinical investigation at any time;
   3) The right of the subject to physical and mental integrity, to privacy, and to personal data protection is safeguarded;
   4) The subject or, when this person is not able to give informed consent, his/her legal representative has given his/her informed consent after being informed of the nature, significance and implications of the clinical investigation and the related risk; the document confirming the informed consent shall be kept along with the documentation of the clinical investigation;
   5) A procedure has been envisaged, ensuring that the subject may without any resulting detriment withdraw from the clinical investigation;
   6) The sponsor and the clinical investigator have entered into an agreement on obligatory liability insurance covering damages caused in relation to the clinical investigation.

5. The minister competent for financial institutions, in consultation with the minister competent for health, having obtained an opinion of the Polish Chamber of Insurance, shall specify, by ordinance, the detailed scope of obligatory insurance referred to in Paragraph 4(6), the date on which the insurance obligation occurs, and the minimum guarantee amount of insurance, taking into account the risk of damage related to the clinical investigation.

6. Complying with the obligation referred to in Paragraph 4(6) shall release neither the sponsor nor the clinical investigator from liability for damages resulting from, or arising in relation to, the clinical investigation.

7. The subject can withdraw from the clinical investigation at any time, without any detriment to himself/herself.

\(^7\) Amendments to the consolidated text of the said Act were published in Dz. U. of 2009, No 6, item 33, No 22, item 120, No 40, item 323, No 76, item 641, and No 219, items 1706 and 1708, and of 2010 No 81, item 531.
8. The clinical investigator shall inform the subject about the possibility to obtain additional information on the subject’s rights.

9. In case of clinical investigations, excluding clinical investigations on adult and healthy subjects, no incentives or financial inducements shall be given, except compensation for the costs incurred.

10. The clinical investigation on minors can be conducted if the following conditions are met:

1) An informed consent of the minor and his/her legal representative has been obtained in line with the rules specified in Article 25 of the Act of 5 December 1996 on the profession of a physician and a dentist;

2) The clinical investigator, or the person indicated by the clinical investigator having experience with minors, shall provide the minor with comprehensible information regarding the clinical investigation and the related risk and benefits;

3) The clinical investigator shall ensure that the wish of a minor, who is capable of forming an opinion and assessing this information, to refuse participation or to be withdrawn from the clinical trial at any time, is considered;

4) There will be direct benefits for the group of minor patients from the clinical investigation, and such investigation is essential to validate data obtained in clinical investigations on persons able to give informed consent, or in clinical investigations conducted by other research methods;

5) The clinical investigation directly addresses a disease in a given minor or it can be conducted only with the participation of minors;

6) The clinical investigation has been designed to minimise pain, fear and any other foreseeable risk in relation to the disease and age of the minor.

11. In the case of clinical investigation on:

1) An incapacitated person - the consent for the participation of this person in the clinical investigation shall be granted by his/her legal representative, and if a person is able to express his/her opinion on the participation in the clinical investigation, a written consent of this person must be obtained;

2) A person having full capacity to perform acts in law, who is not able to give an opinion on his/her participation in the clinical investigation - the informed consent for the participation of the person in the clinical investigation shall be granted by the guardianship court competent for the place where the clinical investigation is conducted.

12. In the situation referred to in Paragraph 11(2), the person who explicitly refused to participate in the clinical investigation cannot be subject to such investigation.

13. The clinical investigation on the person referred to in Paragraph 11 can be conducted, if the following additional conditions are met:

1) The person has received information according to his/her capacity of understanding on the clinical investigation, as well as related risk and benefits;

2) The wish of a person, who is capable of forming an opinion and assessing the information, to refuse participation in, or to be withdrawn from, the clinical investigation is considered by the clinical investigator at any time;

3) Such clinical investigation is essential to validate data obtained in clinical investigations on persons able to give informed consent, and relates directly to a life-threatening or debilitating condition from which the person concerned suffers;

4) The clinical investigation has been designed to minimise pain, fear and any other foreseeable risk in relation to the disease and the age of the subject;

5) There are grounds for expecting that administering the product to be tested will be beneficial to the subject, and will involve no risk.

Article 41.

1. A clinical investigation shall:
1) Be carried out on the basis of an investigation plan reflecting the state-of-the-art scientific, medical and technical knowledge, in a manner allowing to confirm, or to refute, the properties of the medical device declared by the manufacturer;
2) Encompass an appropriate number of observations to guarantee scientific validity of conclusions;
3) Concern all the relevant properties of the device, including those related to safety and performance of the device as well as to its influence on patients;
4) Be carried out in conditions resembling those in which the device is to be used;
5) Be carried out in accordance with procedures selected to suit the device;
6) Be carried out in accordance with the ethical principles for the protection of human rights and dignity of the human being;

2. The responsibilities of a clinical investigator conducting a clinical investigation in a given centre shall include in particular:
1) Ensuring medical care for the subjects;
2) Monitoring compliance of the clinical investigation being carried out with the provisions of the Act;
3) Notifying the sponsor of serious adverse events, excluding the event defined in the protocol or the investigator's brochure as not requiring immediate notification.

3. A clinical investigation shall be presumed to comply with the requirements specified in the provisions issued pursuant to Paragraph 4 within the scope in which it was determined as being in conformity with the relevant harmonised standards, referred to in Article 26.

4. The minister competent for health shall specify, by ordinance, the detailed requirements concerning the manner of drafting, monitoring, preparing and storing basic documentation of a clinical investigation, as well as the manner of conduct in this respect – as regards the sponsor, clinical investigator and clinical investigation monitor – taking into account the necessity to ensure the safety of subjects and the reliability of clinical investigation results.

Article 42.

The sponsor shall appoint:
1) The clinical investigation monitor, who shall be verifying the progress of the clinical investigation and checking whether the clinical investigation is being carried out in accordance with the requirements specified in the Act, and with clinical investigation protocol, written procedures and harmonised standards, if they are applied, as well as informing the sponsor on the results of these verifications and checks;
2) The principal clinical investigator selected from among the members of the investigating team – if the clinical investigation in a given centre is carried out by an investigating team;
3) The coordinator of clinical investigation selected from among all the clinical investigators conducting the clinical investigation within the territory of the Republic of Poland – if the clinical investigation is carried out by various clinical investigators on the basis of a unique protocol and in numerous centres located in the territory of the Republic of Poland or of other countries (multi-centre clinical investigation).

Article 43.

1. The clinical investigation may be started after obtaining the authorisation to conduct a clinical investigation from the President of the Office, subject to Article 46(3).
2. After the clinical investigation is started, the sponsor may make amendments to the clinical investigation, and should these amendments be significant and have the potential to influence the safety of the subjects or the manner of conducting the clinical investigation,
such amendments shall be made after obtaining the authorisation from the President of the Office, subject to Article 46(3).

Article 44.

1. The sponsor shall submit to the President of the Office an application for the authorisation to conduct a clinical investigation or for the authorisation to make amendments to the clinical investigation.

2. For submitting the applications referred to in Paragraph 1, fees constituting State budget income shall be collected, the amount of which shall not exceed:
   1) Seven minimum remunerations for work, determined pursuant to the provisions on the minimum remuneration for work – for applications for the authorisation to conduct a clinical investigation;
   2) A half of the amount referred to in Subparagraph 1 – for applications for the authorisation to make amendments to the clinical investigation.

3. The application for the authorisation to conduct a clinical investigation shall be accompanied by:
   1) The data concerning the medical device intended for clinical investigation, allowing to identify the medical device;
   2) The clinical investigation protocol which defines the objectives, design, methodology, statistical considerations and organisation of the clinical investigation;
   3) The investigator’s brochure containing clinical and non-clinical information concerning the device under investigation, relevant for the clinical investigation;
   4) The information for the subjects and the informed consent forms;
   5) A document confirming the conclusion by the sponsor and the clinical investigator of the obligatory liability insurance contract referred to in Article 40(4)(6);
   6) The case report form, in paper or electronic version, intended for recording the information on the subjects, which is required in the clinical investigation protocol, with the view of reporting it to the sponsor;
   7) The data on professional qualifications of the clinical investigators and on the centres participating in the clinical investigation;
   8) A statement on the conformity of the device intended for clinical investigation with safety requirements, confirming that the device complies with the essential requirements, apart from those covered by the scope of clinical investigation;
   9) A statement determining whether the device intended for clinical investigation incorporates, as its integral part, a medicinal product or a blood product referred to in Article 4(1) and (2);
   10) A statement determining whether the device intended for clinical investigation is manufactured using animal tissue;
   11) A positive opinion of the bioethics committee, having competence over the place where the investigation is being conducted, and in the case of a multi-centre investigation conducted within the territory of the Republic of Poland - on the basis of a unique protocol – a positive opinion of a bioethics committee, having competence over the place where the investigation is being conducted, issued by the coordinating clinical investigator selected by the sponsor from among all the clinical investigators conducting the clinical investigation;
   12) A confirmation of paying the fee for submitting the application;
   13) Contracts regarding the clinical investigation concluded between the parties participating in the clinical investigation.

4. In the application for authorisation to make amendments to the clinical investigation, the sponsor shall determine and justify the scope, need and circumstances of such amendments and their impact on the clinical investigation, in particular on the safety of the subjects.
5. The application for authorisation to make amendments to the clinical investigation shall be accompanied by the documents specified in Paragraph 3 within the scope suitable to the requested amendments, and a positive opinion on the amendments to the clinical investigation issued by the bioethics committee that issued the opinion on this clinical investigation.

Article 45.

1. Should the application referred to in Article 44(1) or the documents attached thereto necessitate supplementation or correction, the President of the Office shall indicate an appropriate period, of at least seven days, for the sponsor to supplement or correct them, advising the sponsor at the same time that the lack of supplementation or correction within the deadline specified shall prevent the application from being considered.

2. The President of the Office may request the sponsor once to provide the supplementing information that is necessary for issuing the decision referred to in Article 46(1). The expiration of the period referred to in Article 46(1) shall be suspended until this information is provided.

Article 46.

1. Within the period of up to 60 days from the day of filing the application, the President of the Office, by administrative decision, shall grant or refuse the authorisation to conduct a clinical investigation or the authorisation to make amendments to the clinical investigation.

2. The President of the Office shall refuse the authorisation to conduct a clinical investigation or the authorisation to make amendments to the clinical investigation, if:
   1) The clinical investigation does not fulfil the requirements defined in the Act or will cease to fulfil them once the amendments are made;
   2) The conformity assessment of the medical device intended for clinical investigation was performed in an incorrect manner;
   3) The device does not fulfil the essential requirements apart from those included in the scope of the clinical investigation or the scope of amendments to the clinical investigation;
   4) The device or its clinical investigation, or the amendments to the clinical investigation, could create an unacceptable risk to life, health or safety of the subjects or the clinical investigators;
   5) No evidence of practicality or scientific justifiability of the clinical investigation or the amendments to the clinical investigation was provided.

3. A clinical investigation may be initiated or the amendments to the clinical investigation may be made, if the President of the Office does not refuse the authorisation to conduct a clinical investigation or the authorisation to make amendments to the clinical investigation, nor demands the information referred to in Article 45(2) within 60 days from the day of filing the application referred to in Article 44(1), and if the bioethics committee issues a positive opinion on the application provided for in Article 49(1).

Article 47.

The President of the Office shall notify the relevant bodies of the Member States and the European Commission of the refusal to issue the authorisation to conduct a clinical investigation, and of the reasons underlying the refusal.

Article 48.
1. The President of the Office shall enter the information on the clinical investigation that they authorised, as well as on the clinical investigation referred to in Article 46(3), and on the clinical investigation that they refused to authorise into the Central Register of Clinical Trials, referred to in Article 371(5) of the Act of 6 September 2001 – Pharmaceutical Law.

2. The President of the Office shall submit the information on clinical investigations referred to in Paragraph 1 to the European Databank on Medical Devices, hereinafter referred to as ‘the EUDAMED.’

Article 49.

1. The bioethics committee shall issue its opinion on the clinical investigation or the opinion on the requested amendments to the clinical investigation upon the sponsor’s request submitted along with the documentation referred to in Article 44(3)(1)–(10) within the period of up to 60 days from the day of filing the application, along with complete documentation.

2. The bioethical committee may request the sponsor once to provide the supplementing information. The expiration of the period referred to in Paragraph 1 shall be suspended until this information is provided.

3. The sponsor may appeal against the opinion of the bioethics committee, referred to in Paragraph 1, to the Appeal Bioethics Committee provided for in Article 29(2a) of the Act of 5 December 1996 on the profession of a physician and a dentist.

4. When issuing the opinion referred to in Paragraph 1, the bioethics committee shall examine in particular:

   1) Justifiability, feasibility and plan of the clinical investigation;
   2) Analysis of the expected risks and benefits;
   3) Correctness of the clinical investigation protocol;
   4) Correctness of the choice of clinical investigator and members of the investigating team;
   5) Quality of the investigator’s brochure;
   6) Quality of the centre;
   7) Level and completeness of the written information presented to the subjects;
   8) Correctness of the procedure used for obtaining the informed consent, as well as the justification for conducting a clinical investigation with participation of subjects unable to provide informed consent, taking into account the special restrictions listed in Article 40(10) and (11);
   9) Manner of recruiting the subjects;
   10) Scope and terms and conditions of the contract referred to in Article (40)(4)(6).

5. If the bioethics committee that is issuing the opinion, referred to in Paragraph 1, with regard to a clinical investigation:

   1) With the participation of minors does not include a paediatrician;
   2) With the participation of subjects unable to provide informed consent does not include a physician specialised in the domain of medicine addressed by the clinical investigation conducted;
      - the bioethics committee shall seek their opinion.

6. If a clinical investigation referred to in Article 42(3) is carried out within the territory of the Republic of Poland, the sponsor shall file the application with the bioethics committee having competence over the place where the coordinating clinical investigator has its registered office.
7. The opinion issued by the bioethics committee referred to in Paragraph 6 shall concern all the centres on whose behalf the sponsor submitted the application for the opinion.

8. The bioethics committee, referred to in Paragraph 6, shall advise all bioethics committees having competence over the places in the territory of the Republic of Poland where the clinical investigation is to be conducted on the envisaged participation of given centres in the clinical investigation. These committees may, within 14 days from the day of learning this information, express their reservations as to the participation of given clinical investigators or centres in the clinical investigation. The failure to express reservations within this period shall be tantamount to acknowledging the participation of given clinical investigators or centres in the clinical investigation.

Article 50.

The minister competent for health shall specify, by ordinance:

1) Template application for the authorisation to conduct a clinical investigation and for the authorisation to make amendments to the clinical investigation, as well as for issuing by the bioethics committee of the opinion on the clinical investigation and of the opinion on the requested amendments to the clinical investigation;

2) Amount of fee for submitting the application for the authorisation to conduct a clinical investigation;

3) Amount of fee for submitting the application for the authorisation to make amendments to the clinical investigation;

4) Information that should be provided in the final report on the completion of the clinical investigation referred to in Article 54(4);
   - taking into account the scope of the clinical investigation, as well as the need to protect life, health and safety of the subjects, the necessity of harmonising the manner of exchanging information on the clinical investigation with the relevant bodies of other Member States, the amount of payment in other Member States, the workload related to performing given actions, and the level of costs incurred by the President of the Office.

Article 51.

1. In the case of an event having a potential to influence safety of the subjects, the sponsor or the clinical investigator shall take measures aimed at ensuring safety of the subjects, and shall suspend the performance of clinical investigation, or refrain from its performance.

2. The sponsor shall submit the information on a serious adverse event, and the information on the event referred to in Paragraph 1, to the President of the Office and to the bioethics committee that issued the opinion on this clinical investigation - immediately, or no later that within 7 days from the day when the event occurred.

3. The President of the Office shall notify the serious adverse event to the relevant body of the Member State on whose territory the clinical investigation is being conducted.

Article 52.

1. Should it be determined that the conditions specified in the application for the authorisation to conduct a clinical investigation or in the application for the authorisation to make amendments to the clinical investigation or in the documentation submitted along with these applications are no longer satisfied, or that it is no longer practical or scientifically justified to conduct the clinical investigation, or that there is reasonable suspicion that life, health or safety of the subjects or the clinical investigators is threatened, the President of the Office may, by administrative decision:
   1) revoke the authorisation to conduct a clinical investigation;
2) suspend the performance of the clinical investigation;
3) call for making a major amendment to the clinical investigation.

2. Should life, health or safety of the subjects of the clinical investigators be at risk, the President of the Office shall communicate the intention to issue the decision referred to in Paragraph 1 to the sponsor, clinical investigator or principal clinical investigator as well as to the bioethics committee that issued the opinion on the clinical investigation.

3. The President of the Office shall notify the bioethics committee that issued the opinion on the clinical investigation and the relevant bodies of other Member States as well as the European Commission of adopting the decision provided for in Paragraph 1(1) and of the reasons for its adoption.

4. The President of the Office shall notify the bioethics committee that issued the opinion on the clinical investigation and – if the clinical investigation was being conducted also in the territory of another Member State – the relevant bodies of this Member State of adopting the decision provided for in Paragraph 1(2) and of the reasons for its adoption.

**Article 53.**

1. Into the territory of the Republic of Poland shall be introduced those medical devices intended for clinical investigation which are to be subject to clinical investigations authorised by the President of the Office.

2. Medical devices intended for clinical investigation shall be imported from outside of the territory of the Member State on the basis of a certificate confirming that those devices are to be subject to clinical investigations authorised by the President of the Office.

3. The President of the Office shall issue the certificate referred to in Paragraph 2 upon request of the sponsor or the clinical investigator. The certificate shall be issued free of charge.

**Article 54.**

1. The sponsor shall promptly notify the President of the Office and – if the clinical investigation was conducted also in the territory of another Member State – the relevant bodies of that Member State of completing the clinical investigation.

2. Within the period of 15 days from the day of terminating the clinical investigation ahead of the envisaged completion date, the sponsor shall inform the President of the Office and the bioethics committee that issued the opinion on the investigation of terminating the clinical investigation, and of the reasons for the premature termination of the investigation.

3. The sponsor shall notify the relevant body of the Member State and the European Commission of the premature termination of the clinical investigation, and of the reasons therefore, if the investigation was terminated prematurely due to safety considerations.

4. Within the period of 90 days from the day of completing the clinical investigation, the sponsor shall send the final report on the completion of the clinical investigation with a detailed description of the investigation, drafted after its completion, to the President of the Office.

**Article 55.**

1. The documentation of a clinical investigation shall consist of:

   1) Source documents;

   2) Other documents on the basis of which the correctness of conducting the clinical investigation and the quality of data obtained can be assessed, and which serve the purpose of confirming the conformity of actions performed by the clinical investigator, sponsor and monitor with the requirements defined in the Act.
2. Source documents shall be the originals of documents, data and records, or their copies certified as true and correct copies of the originals, that concern the clinical investigation, in particular the case records, excerpts from comprehensive internal documentation of the centre conducting the clinical investigation, documentation prepared pursuant to the clinical investigation protocol, results of laboratory tests, physician order logs, printouts of test results from automatic medical equipment, x-ray images, as well as signed and dated informed consent forms.

3. Source documents shall constitute medical files within the meaning of the provisions of the Act of 6 November 2008 on patients’ rights and on the Commissioner on Patients’ Rights (Dz. U. of 2009 No 52, item 417, and No 76, item 641, and of 2010 No 96, item 620).

4. The documentation referred to in Paragraph 1(2) shall be stored over a period of 5 years from the day of completing or suspending the clinical investigation of a device.

5. The documentation referred to in Paragraph 1(2) shall become State archive resources pursuant to Article 44 of the Act of 14 July 1983 on National Archive Resources and Archives (Dz. U. of 2006 No 97, item 673, as amended9), and it shall be stored over the period specified in Paragraph 4. The documentation shall be made available free of charge upon request of the President of the Office. The provisions of Article 17(1) of the said Act shall not apply.

Article 56.

Prior to obtaining the informed consent, the clinical investigator shall present the subject or the subject’s statutory representative, in an understandable manner and without exerting any pressure, with the information in written or spoken form regarding the necessity to provide source documents concerning the subject to the entities authorised to monitor, audit or control the clinical investigation.

Article 57.

1. The President of the Office shall be entitled to control clinical investigations.

2. The controls of clinical investigations shall be conducted on the basis of the authorisation issued by the President of the Office for the person conducting the controls. The controls may be carried out by any person who has not been sentenced for intentional offence subject to public prosecution or for intentional tax offence, and who has full capacity to perform acts in law.

3. The person conducting the controls may verify in particular:
   1) Whether the clinical investigation is being carried out on the basis of the authorisation issued by the President of the Office;
   2) Whether the conditions specified in the application for the authorisation to conduct a clinical investigation and in the application for the authorisation to make amendments to the clinical investigation are being observed;
   3) Whether the clinical investigation is being carried out in accordance with the provisions of the Act;
   4) Whether the subjects have made the declarations on the informed consent form;
   5) The state of the rooms and equipment used for the purposes of the clinical investigation;
   6) The conformity of the clinical investigation being carried out with the clinical investigation protocol as well as with the accepted amendments to this protocol;

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9 Amendments to the consolidation of the said Act were published in Dz. U. of 2006 No 104, item 708, No 170, item 1217 and No 220, item 1600, of 2007 No 64, item 426, of 2008 No 227, item 1505, of 2009 No 39, item 307 and No 166, item 1317 and of 2010 No 40, item 230 and No 47, item 278.
7) The manner of documenting the data and of storing the documentation.

4. The person conducting control may request that the documentation referred to in Article 55 be presented, and that clarifications regarding the clinical investigation be provided.

5. The controls shall be carried out after the entity conducting the clinical investigation and the sponsor have been notified thereof.

6. Should there be suspicion that life or health of the subjects might be at risk during the clinical investigation, the control may be carried out without notifying in advance the entity conducting the clinical investigation or the clinical investigator and the sponsor.

7. A protocol from the control carried out shall be prepared in three copies, one for the entity under control and one – for the sponsor.

8. The control protocol may include follow-up recommendations that the entity under control shall implement in agreement with the sponsor within the period indicated in the protocol.

9. The entity under control shall promptly inform the President of the Office of implementing the follow-up recommendations or of the reasons for failing to implement them within the period indicated in the control protocol.

10. Should the control reveal irregularities threatening life or health of the subjects, the President of the Office shall assess the threat and issue the decision provided for in Article 52(1).

11. The controls may also be aimed at verifying the implementation of the follow-up recommendations.

Chapter 7
Reports and notifications concerning the devices

Article 58.

1. The manufacturer and the authorised representative having the residence or the registered office on the territory of the Republic of Poland shall report the device to the President of the Office at least 14 days before the device is first placed on the market or submitted for performance assessment.

2. The entity having the place of residence or the registered office on the territory of the Republic of Poland, that conducts the activity referred to in Article 30(1) or (4), shall submit a report to the President of the Office containing the information on the activity performed, at least 14 days before the systems or procedure packs, sterilised systems or procedure packs or other sterilised medical CE-marked devices are first placed on the market.

3. The distributor and the importer having the place of residence or the registered office on the territory of the Republic of Poland who have introduced into the territory of the Republic of Poland a device intended for use in this territory, shall promptly notify the President of the Office thereof, not later, however than within 7 days from the day of importing the first device into the territory of the Republic of Poland.

4. The service provider who conducts in the territory of the Republic of Poland a performance assessment of a device intended for its performance assessment, whose manufacturer and authorised representative do not have the place of residence or the registered office on the territory of the Republic of Poland, shall promptly notify the President of the Office thereof, not later, however, than within 7 days from the day of commencing the performance assessment.

Article 59.

1. The report referred to in Article 58(1) and (2) shall contain in particular:
1) Name and address of the reporting entity;
2) Trade name of the device;
3) Generic name of the device;
4) Name and address of the manufacturer;
5) Short description of the device and its envisaged use in Polish and in English;
6) Class of the medical device and the classification rules applied;
7) Information whether the in vitro diagnostic medical device is a device from List A or from List B, whether it is a self-testing device, a device intended for performance assessment or a new device;
8) Information whether the device is a custom-made device;
9) Number of the notified body who participated in the conformity assessment;
10) Device code according to the Global Medical Devices Nomenclature (GMDN) or another acknowledged nomenclature of medical devices, along with the name of this nomenclature.

2. The report shall be accompanied by:
   1) Marking templates;
   2) Model instructions for use – if delivered with the device;
   3) Model promotional materials – if delivered with the device;
   4) Conformity declaration, declaration on the custom-made device, declaration on the device intended for performance assessment, declaration on the system or procedure pack referred to in Article 30(1), or declaration on sterilisation referred to in Article 30(4);
   5) List of laboratories or other institutions participating in the performance assessment of a device intended for performance assessment;
   6) Copies of certificates of conformity issued by notified bodies who participated in the conformity assessment;
   7) Document confirming the payment of the fee referred to in Article 66(1);
   8) Excerpt from the National Court Register or excerpt from the economic register;
   9) Copy of a document appointing the authorised representative having the place of residence or the registered office on the territory of the Republic of Poland;
10) Copy of a document confirming the identity and residence address – in the case of a natural person not pursuing business activity.

Article 60.

1. The notification referred to in Article 58(3) and (4) shall contain:
   1) Name and address of the notifying entity;
   2) Trade name of the device;
   3) Name and address of the manufacturer;
   4) Name and address of the authorised representative.
2. The notification referred to in Article 58(3) and (4) shall be accompanied by:
   1) Marking templates;
   2) Model instructions for use – if delivered with the device;
   3) Model instructions for use of the device intended for performance assessment that is to be subject to performance assessment in the territory of the Republic of Poland – if delivered with the device;
   4) Model promotional materials indicating the envisaged use of the device intended for use in the territory of the Republic of Poland – if delivered with the device;
5) Information on the number or quantity of devices delivered for performance assessment as well as on the duration of performance assessment;
6) Document confirming the payment of the fee referred to in Article 66(1);
7) Excerpt from the National Court Register or excerpt from the economic register;
8) Copy of a document confirming the identity and residence address – in the case of a natural person not pursuing business activity.

Article 61.

1. The entities referred to in Article 58 shall report all changes in the data covered by the report or notification to the President of the Office promptly, not later, however, than within 7 days from the day of learning the information on the change.
2. A change shall also be considered to consist in delegating the responsibilities to another entity, especially in connection with restructuring, bankruptcy or assumption of rights and obligations under the Act by the legal successor.

Article 62.

1. The entities referred to in Article 58(1) and (2) shall promptly report to the President of the Office the fact of ceasing to place the device on the market.
2. The authorised representative referred to in Article 58(1) shall promptly report to the President of the Office the fact of ceasing to perform the function of authorised representative for a given device.
3. If the activity being subject to reporting or notification pursuant to the Act is ceased, including due to liquidation or bankruptcy:
   1) Documentation on conformity assessment;
   2) List of recipients;
   - shall become State archive resources pursuant to Article 44 of the Act of 14 July 1983 on National Archive Resources and Archives, and shall be stored over the periods specified in Article 13(3), Article 18(3) and Article 32(1) and (2). The provisions of Article 55(5), second and third sentence, shall not apply.

Article 63.

1. Should a report or notification be incomplete or incorrect, the President of the Office shall request the entities once to supplement or correct the report or notification, within not less than 7 days.
2. The failure to supplement or to correct the report or notification within the deadline specified in Paragraph 1 shall be tantamount to the failure to provide any report or notification.

Article 64.

1. The President of the Office shall gather the data from the reports and notifications in a database, on electronic storage media secured against third-party access.
2. The President of the Office shall submit the data specified in Article 59(1), within the scope suitable for the device, to the EUDAMED database.
3. The provisions contained in Paragraph 2 shall not apply to custom-made devices.

Article 65.

1. The reports and notifications referred to in Article 58 and Article 61 shall be submitted on forms.
2. The minister competent for health shall specify, by ordinance:
   1) Template forms of reports and notifications referred to in Article 58 and Article 61;
   2) Manner of reporting changes in the data covered by the report and notification;
   3) Manner of reporting the fact of ceasing to place a device on the market and to perform
      the function of authorised representative;
   4) Manner of submitting to the President of the Office the forms and documents
      accompanying a report or notification;
      - taking into account the data necessary for exercising the supervision provided for in
      Article 68 and for the operation of the EUDAMED database.

Article 66.

1. A fee constituting State budget income shall be paid for submitting the report referred to in
   Article 58(1) and (2) and the notification referred to in Article 58(3) and (4), as well as for
   changing the data covered by the report referred to in Article 58(1), and (2) and by the
   notification referred to in Article 58(3) and (4).
2. The amount of the fee for:
   1) Reporting or notification shall not exceed the minimum remuneration for work
      determined pursuant to the provisions on the minimum remuneration for work;
   2) Changing the data shall be equal to a half of the amount payable for the actions referred
      to in Subparagraph 1.
3. The reports on ceasing the activity, referred to in Article 62(1) and (2), shall be submitted
   free of charge.

Article 67.

1. Upon request of the manufacturer or the authorised representative having the place of
   residence or the registered office on the territory of the Republic of Poland, the President of
   the Office, in order to facilitate the export, shall issue a free sales certificate for the
   CE-marked device and for the custom-made device.
2. For filing the application for the free sales certificate, a fee constituting State budget
   income shall be paid, the amount of which shall not exceed the minimum remuneration for
   work determined pursuant to the provisions on the minimum remuneration for work.
3. The President of the Office shall issue the free sales certificate within 15 days from the day
   of filing the application.
4. The free sales certificate shall be drawn up in Polish and in English.
5. The application for the free sales certificate shall contain:
   1) Name and address of the applicant;
   2) Trade name of the device;
   3) Name and address of the manufacturer.
6. The application for the free sales certificate shall be accompanied by the confirmation of
   paying the fee for submitting the application for the free sales certificate.
7. The minister competent for health shall determine, by ordinance, the amount of the fee for
   reporting and notification, for changing the data covered by the report or notification, and
   for submitting an application for the free sales certificate – taking into account the workload
   and the level of costs incurred by the President of the Office.

Chapter 8
Supervision over the devices
Article 68.

1. The supervision over the devices manufactured, imported, placed on the market, introduced for use or submitted for performance assessment in the territory of the Republic of Poland shall be exercised by the President of the Office.

2. When exercising the supervision provided for in Paragraph 1, the President of the Office shall cooperate with:

1) Main Pharmaceutical Inspector;
2) Chief Sanitary Inspector;
3) Chief Veterinary Officer;
4) President of the Office of Competition and Consumer Protection;
5) Minister competent for public finance;
6) President of the Office of Technical Inspection;
7) Chief Labour Inspector;
8) President of the National Atomic Energy Agency;
9) Head of the body competent for health reporting to the Minister of National Defence;
10) Chief Police Officer;
11) President of the Central Office of Measures;
12) President of the National Health Fund;
13) Agency for Medical Technologies Protection;
14) Centre for Quality Monitoring in Health Care;
15) Centre for Health Care Information Systems;
16) Main Centre for Quality Control in Laboratory Diagnostics;
17) Main Centre for Quality Control in Diagnostic Microbiology;

- within the scope relevant to these entities.

3. The entities listed in Paragraph 2 shall notify the President of the Office on irregularities found with regard to devices.

4. The President of the Office shall issue, upon request of customs authorities, an opinion on compliance of the device with the requirements established for it.

5. The customs authorities shall inform the President of the Office of the actions taken with regard to the withheld devices.

6. The minister competent for public finance, in consultation with the minister competent for health, shall determine, by ordinance:

1) Detailed manner of conduct for the customs authorities in the case of finding, in the course of inspection of devices that are to be subject to the marketing authorisation procedure, that a reasonable indication exists of a device not satisfying the requirements established for it;
2) Manner of issuing the opinion and of handling the opinion issued by the President of the Office;
3) Detailed manner of placing annotations by the customs authorities on documents accompanying the devices withheld by the customs authorities or in the ICT system;

- taking into account the necessity to prevent the import into the territory of the Republic of Poland of devices that do not comply with the requirements established for them.

Article 69.

1. The supervision referred to in Article 68(1) shall consist in:

1) Gathering and analysing information on device safety;
2) Controlling manufacturers, authorised representatives, importers, distributors, entities compiling medical devices into systems or procedure packs, and entities sterilising medical devices, systems and procedure packs in order to place them on the market, as well as subcontractors having the place of residence or the registered office on the territory of the Republic of Poland;

3) Issuing decisions provided for in Chapter 10.

2. The control of entities referred to in Paragraph 1(2) shall comprise of:
   1) Designing, manufacturing, packaging, labelling, storing, distributing, assembling, processing and completely refurbishing a device;
   2) Presenting a device during fairs, exhibitions, presentations and scientific and technical symposia;
   3) Making a device suitable to its envisaged use;
   4) Sterilising the device prior to placing it on the market and putting it into service;
   5) Compiling medical devices into systems or procedure packs;
   6) Conducting examinations and the final control of a device;
   7) Placing devices on the market, trading in them and putting them into service.

3. The President of the Office may also control:
   1) The device, its documentation and conditions of using the device by the service provider or of conducting the performance assessment in the place of use or of carrying out the performance assessment;
   2) The entities performing the actions related to installing, maintaining, refurbishing, servicing, regulating, calibrating, sizing, surveying, repairing or carrying out periodical safety checks of devices, in the place of performing these activities or in the place of residence or the registered office of entities performing them;
   - in cases justified by the need to protect life or health of patients and users, as well as by the need to safeguard public health.

Article 70.

1. The controls provided for in Article 69(1)(2) and Article 69(3) shall be performed by persons authorised by the President of the Office who have not been sentenced for intentional offence subject to public prosecution or intentional tax offence, and who have full capacity to perform acts in law.

2. The controls shall be conducted during working hours of the entity under control and in the presence of an authorised representative of the entity under control.

3. Within the framework of controls, the controlling person may in particular:
   1) Read the documentation concerning the device;
   2) Examine the activities concerning the device;
   3) Request information and clarifications from the employees of the entity under control.

4. In the case of controls referred to in Article 69(2), the controlling person, apart from the actions referred to in Paragraph 3, may:
   1) Inspect the production and storage areas, and their equipment;
   2) Request access to samples necessary for conducting examinations and verifications regarding the device.

5. The President of the Office may commission research and development centres, scientific institutes, higher education institutions, device certifying bodies or laboratories to perform examinations or verifications of the samples referred to in Paragraph 4(2).

6. Should the results of the examinations or verifications referred to in Paragraph 5 confirm that a device does not comply with the requirements established for it, the costs of such
examinations and verifications shall be borne by the manufacturer, authorised representative, importer, or distributor of the device.

Article 71.

1. The control referred to in Article 69(1)(2) may consist in evaluation of device documentation, sent upon request of the President of the Office.
2. For the control referred to in Article 69(1)(2) and Article 69(3), documentation shall be submitted in Polish or in English.
3. The President of the Office may request the entity under control to provide a translation of the specified documentation into Polish.
4. The President of the Office may demand the manufacturer, authorised representative, importer or distributor having the place of residence or the registered office on the territory of the Republic of Poland to supply samples necessary to conduct examinations and verification of the device.
5. The provisions of Article 70(5) and (6) shall apply accordingly to the samples referred to in Paragraph 4.

Article 72.

1. The control ends with preparing a protocol in two copies, one for the entity under control.
2. The protocol from control may include follow-up recommendations.
3. Within 14 days from receiving the protocol, the controlled entity may submit its objections to the protocol, along with their justification.
4. The President of the Office shall examine the objections within 30 days from receiving them, and shall take a position on the matter which will be final and which will be delivered to the controlled entity along with its justification.
5. The controlled entity shall introduce the follow-up recommendations within the deadline stated in the protocol of control.
6. The manufacturer and the authorised representative shall promptly send information on inconsistencies and irregularities discovered during the control and on follow-up recommendations along with their deadlines to the notified body which participated in device conformity assessment.

Article 73.

The President of the Office may demand of the manufacturer or of the authorised representative having the place of residence or the registered office on the territory of the Republic of Poland to submit a report on experience gathered after placing a new device on the market, within two years since notification of the new device.

Chapter 9
Medical incidents and measures concerning the safety of devices

Article 74.

1. A medical incident can be reported to the President of the Office by anyone who learned about the medical incident in the territory of the Republic of Poland.
2. A service provider who discovered a medical incident during the provision of health care services shall report it promptly to the manufacturer or to the authorised representative, and shall send a copy of the report to the President of the Office.
3. The entities referred to in Article 68(2) as well as entities conducting external assessment of the quality of work of medical diagnostic laboratories which, during their operations, come to suspect a medical incident shall report it promptly to the President of the Office.

4. Importers and distributors of devices, research laboratories, research and development units, and entities providing services in the area of repairs, servicing, maintenance and calibration of devices who, during their operations, discovered a medical incident which took place in the territory of the Republic of Poland shall report it promptly to the manufacturer or the authorised representative, and shall send a copy of the report to the President of the Office, unless they learned that the incident has already been reported to the manufacturer, the authorised representative or the President of the Office.

5. If the address of the manufacturer or the authorised representative cannot be identified, medical incidents shall be reported to the manufacturer, and a copy of the report shall be submitted to the President of the Office.

6. Medical incidents shall be reported using the form for medical incident reporting which includes in particular the following:
   1) Date and place, as well as the description of the medical incident, and its consequences;
   2) Name and address of the manufacturer and of the authorised representative;
   3) Name and address of the supplier of the device;
   4) Trade name of the device;
   5) Generic name of the device;
   6) Serial number or manufacturer’s number or the device batch or lot number;
   7) Number of the notified body appearing next to the CE marking;
   8) Name and surname of the person reporting the incident or the name of the entity reporting the incident, as well as the name and surname of the person reporting on behalf of that entity;
   9) Contact details of the entities and persons referred to in Subparagraph 8, including the phone number, and, if possible, also the fax number and the e-mail address.

7. The President of the Office shall notify the manufacturer or the authorised representative that the medical incident referred to in Paragraphs 1 and 3 has been reported by sending a copy of medical incident report, if the report says that the reporting entity has not informed the manufacturer or the authorised representative of the incident.

Article 75.

1. The manufacturer shall ensure that the authorised representative and any other entity authorised by the manufacturer to act on his/her behalf as concerns medical incidents and in matters concerning device safety would implement Field Safety Corrective Actions, hereinafter referred to as “FSCA.”

2. Entities authorised by the manufacturer to act on his/her behalf as concerns medical incidents and in matters concerning device safety shall inform the President of the Office on the implementation of FSCA.

3. Importers and distributors of devices having the place of residence or the registered office on the territory of the Republic of Poland and entities providing services in the area of repairs, servicing, maintenance and calibration of devices, personnel of service providers or persons performing other activities for service providers, including medical personnel, personnel responsible for maintenance and safety of devices, as well as administration shall cooperate with the President of the Office, the manufacturer and the entities referred to in Paragraph 1 in implementing FSCA.

Article 76.

1. The manufacturer shall initiate explanatory proceedings concerning the reported medical incident. The manufacturer shall decide if the reported medical incident which took place in the
territory of the Republic of Poland is an event which meets the criteria for reporting it to the President of the Office.

2. If the manufacturer decides that the medical incident is an event which does not meet the criteria for reporting, he/she shall document the decision justification and shall send it to the President of the Office.

3. If the manufacturer decides that the medical incident is an event which meets the criteria for reporting, or if the President of the Office informs that manufacturer or the authorised representative that he/she does not agree with the decision of the manufacturer referred to in Paragraph 2 and the incident requires reporting, the manufacturer or the authorised representative shall send the Preliminary Report on the incident, prepared using the manufacturer's report on a medical incident form, to the President of the Office.

4. The Preliminary Report shall include in particular:

1) Preliminary analysis of the incident;
2) Information on initial corrective or preventive measures implemented by the manufacturer, including on initiated or planned examinations;
3) Information on the projected deadline for sending a subsequent report.

5. The Preliminary Report shall be sent to the President of the Office within the following deadlines:

1) In case of a serious threat to public health – immediately, but not later than two days after the information on the threat is received by the manufacturer or the authorised representative;
2) In case of death or an unpredictable deterioration of health not covered by risk analysis – immediately when the manufacturer determines the causal relationship between the device and the event, but not later than 10 days after the manufacturer or the authorised representative receives information on the event;
3) In other cases – immediately when the manufacturer determines the causal relationship between the device and the event, but not later than 30 days after the manufacturer or the authorised representative receives information on the event.

Article 77.

1. The manufacturer shall analyse all complaints concerning the device as well as instances of usage errors and incorrect use. The analysis depends on risk management, ergonomics, project validation as well as on corrective and preventive measures. The manufacturer or the authorised representative having the place of residence or the registered office on the territory of the Republic of Poland shall make analysis results available upon request of the President of the Office and of the notified body taking part in device conformity assessment.

2. Usage errors which result in a serious threat to public health, death or a serious deterioration of health of a patient, user or, indirectly, another person in the territory of the Republic of Poland shall be reported by the manufacturer or his/her authorised representative within deadlines provided for in Article 76(5)(1) and (2).

Article 78.

1. If the manufacturer is unable to conduct explanatory proceedings concerning the reported medical incident, complaint, usage error or incorrect use which took place in the territory of the Republic of Poland, he/she shall promptly inform the President of the Office.

2. The President of the Office shall monitor the manufacturer’s explanatory proceedings concerning the medical incident, complaint, usage error or incorrect use which took place in the territory of the Republic of Poland and may intervene or take up separate explanatory proceedings, if possible, after consultations with the manufacturer or the authorised
representative. The President of the Office shall inform the manufacturer or the authorised representative on progress and the results of his/her explanatory proceedings.

3. The person reporting a medical incident shall provide the manufacturer and the entities referred to in Article 75(1) any help required during the explanatory proceedings to determine the causal relationship between the device and the reported medical incident, he/she shall in particular provide the necessary information and make the device available for examination and assessment.

4. If the actions of the manufacturer connected with preliminary assessment, cleaning or disinfecting of the device covered with explanatory proceedings could alter the device in a way that would affect subsequent examinations, the manufacturer or the authorised representative shall inform the President of the Office of that fact prior to starting the examination.

5. The provisions of Paragraphs 3 and 4 shall apply accordingly to samples, accessories and other devices connected with the medical incident.

6. If the explanatory proceedings are not completed, the manufacturer or the authorised representative shall send the Subsequent Report, prepared using the manufacturer's report on a medical incident form, to the President of the Office within the deadline set in the Preliminary Report.

7. Upon completion of explanatory proceedings, the manufacturer or the authorised representative shall send the Final Report, prepared using the manufacturer's report on a medical incident form, to the President of the Office, not later than within the deadline set in the Preliminary Report or in the Subsequent Report.

8. The Final Report shall include in particular:
   1) Results of the explanatory proceedings;
   2) Information on planned or taken measures, such as additional supervision of products in use, preventive and corrective measures related to future manufacturing, remedial measures and FSCA or information on lack of such measures.

9. Having received the Final Report, the President of the Office may find the proceedings completed and inform the manufacturer or the authorised representative of that fact.

10. If the explanatory proceedings are not completed before the expiry of the deadline for the next report set in the Preliminary Report or in the Subsequent Report, the manufacturer or the authorised representative shall send the Subsequent Report, prepared using the manufacturer's report on a medical incident form, to the President of the Office.

11. The Subsequent Report shall include in particular:
   1) Results of the explanatory proceedings obtained until the Report is prepared;
   2) The projected deadline for sending a subsequent report.

**Article 79.**

1. The manufacturer shall implement FSCA with a view to mitigate the risk of death or a serious deterioration of health connected with using the device placed on the market.

2. The manufacturer or the authorised representative having the place of residence or the registered office on the territory of the Republic of Poland shall prepare the FSCA Report using the FSCA Report form, as well as a safety note to inform recipients or users of FSCAs.

3. The safety note intended for recipients or users in the territory of the Republic of Poland shall be prepared in Polish.

4. The safety note shall include in particular:
   1) The trade name of the device to which the note pertains, FSCA identification and FSCA type;
   2) Data to identify the devices to which FSCAs pertain;
   3) Information about FSCAs and the reason for implementing them;
   4) Recommendations of measures to be taken by recipients or users;
5) Information that the entities to which the safety note pertains must receive it;
6) Name of the entity which should be contacted by safety note recipients in matters connected with FSCAs.

5. The FSCA Report shall include in particular:
1) Name and address of the competent body for which the Report is intended;
2) Report date and number;
3) Status of the entity which drafted the Report;
4) Name and address of the place of residence or the registered office of the device manufacturer;
5) Name and address of the place of residence or the registered office of the authorised representative;
6) Name and address of the person to be contacted in matters concerning FSCAs;
7) Information on devices to which FSCAs pertain;
8) FSCA description and schedule;
9) List of Member States to which FSCAs pertain.

Article 80.

1. Prior to sending the safety note to recipients or users, the manufacturer or the authorised representative having the place of residence or the registered office on the territory of the Republic of Poland shall send it to the President of the Office along with the FSCA Report.
2. The President of the Office may submit comments to the safety note within 48 hours since receiving it or within 24 hours since receiving it in case of a serious threat to public health.
3. If the President of the Office does not submit comments to the manufacturer or the authorised representative within the deadline specified in Paragraph 2, the safety note may be sent to recipients or users.

Article 81.

The manufacturer or the authorised representative having the place of residence or the registered office on the territory of the Republic of Poland shall inform the notified body which participated in the device conformity assessment procedure of implementing FSCAs, and shall send it the safety note.

Prior to or at the time of starting FSCAs, the manufacturer or the authorised representative having the place of residence or the registered office on the territory of the Republic of Poland shall send the FSCA Report along with the safety note to competent bodies of those Member States which placed the devices on the market or put them into service.

Prior to or at the time of starting FSCAs, the manufacturer or the authorised representative starting FSCAs in the territory of the Republic of Poland shall send the FSCA Report along with the safety note to the President of the Office.

If the manufacturer or the authorised representative starts FSCAs in connection with a medical incident which took place in the territory of the Republic of Poland or starts FSCAs in relation to devices whose majority has been placed on the market or put into service in the territory of the Republic of Poland, the provisions of Article 80 shall apply accordingly.

The manufacturer or the authorised representative having the place of residence or the registered office on the territory of the Republic of Poland shall inform the President of the Office and the bodies referred to in Paragraph 2 on completing FSCAs and their effectiveness in the given Member State.
The manufacturer or the authorised representative who implements FSCAs in the territory of the Republic of Poland shall inform the President of the Office on completing FSCAs and their effectiveness.

In instances justified by public health protection, the President of the Office shall publish the information on FSCAs implemented in the territory of the Republic of Poland as well as the safety note, among others in the official gazette – Public Information Bulletin and on the website of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.

**Article 82.**

1. The manufacturer shall evaluate the risk connected with devices affected by the medical incident or another event which meets the reporting criteria, and shall make the decision whether it is necessary to take corrective measures and to what extent - on the basis of risk analysis assessment.

2. The President of the Office shall assess the adequacy of actions planned and taken by the manufacturer in the territory of the Republic of Poland. The President shall also evaluate the manufacturer's report and may provide guidelines in that respect, designating in particular the following:
   1) The scope of device examinations, analyses and verification;
   2) Independent laboratories and research units which should perform device examinations, analyses and verification;
   3) Dates of individual corrective and preventive measures;
   4) Necessary changes to the design, structure or manufacturing method of the device;
   5) The necessity to add essential warnings and recommendations to the information supplied with the device;
   6) The necessity to train or additionally train device users;

3. The President of the Office may, if possible and in consultation with the manufacturer or the authorised representative, take steps aimed at clarifying the reasons behind and the effects of the medical incident, as well as to assess the structure and properties of the device, in particular:
   1) Gather additional information and opinions on the medical incident or on the device;
   2) Commission independent reports on the medical incident or on the device;
   3) Consult the notified body which participated in device conformity assessment, as well as device users and competent bodies of Member States;
   4) Issue relevant recommendations and warnings for device users;
   5) Apply to the European Commission for re-classifying or re-qualifying the device.

4. The President of the Office may order the manufacturer or the authorised representative to implement FSCAs or to change the FSCAs being implemented.

**Article 83.**

1. The President of the Office shall:
   1) Prepare a report concerning the safety of the device – the National Competent Authority Report, hereinafter referred to as NCAR, in English, and send it to the European Commission as well as to the competent bodies of Member States,
   2) Provide data to the EUDAMED database,

- if the information on medical incident, on implementing FSCAs or on non-implementing FSCAs that should be implemented, is important for protection of safety, health or life of patients, device users or other individuals in other Member States.
2. Preparing the report referred to in Paragraph 1(1), the President of the Office may consult the manufacturer or the authorised representative. The President should inform them the report is being drafted.

3. The President of the Office may send a copy of the report referred to in Paragraph 1(1) to the manufacturer or the authorised representative.

4. The report referred to in Paragraph 1(1) shall include the following:
   1) Data identifying the report, contact details and the address of the President of the Office;
   2) Device data and the number of the notified body;
   3) Data of the manufacturer and of the authorised representative;
   4) The kind of actions taken;
   5) Additional information and the reason for preparing the report.

Article 84.
Unless the Act stipulates otherwise, correspondence related to the medical incident shall be exchanged in Polish or in English. The President of the Office may request the sender to provide a translation of any document into Polish.

Article 85.
The minister competent for health shall specify, by ordinance:
   1) Criteria of reporting on events involving devices and medical incidents;
   2) Model form to report a medical incident;
   3) Model form of the manufacturer’s report on a medical incident;
   4) Model form of the FSCA report;
   5) Model safety note;
   6) Model NCAR form;
   7) The method of sending the notifications, reports and notes referred to in Subparagraphs 2-6;
   8) The detailed procedure for entities participating in actions concerning a medical incident, FSCAs and other measures in the area of safety of devices;
- Taking into account the necessity to protect life, health and safety of patients, users and third persons, and considering the need to harmonise the method of exchanging information concerning device safety with the European Commission and Member States.

Chapter 10 Decisions of the President of the Office

Article 86.
1. In order to protect life, health and safety of patients, users and other persons, as well as to prevent threats to public health, safety and order, the President of the Office may issue an administrative decision in relation to a device or a group of devices on subjecting them to special requirements, banning, suspending or restricting placing them on the market, putting them into service, launching or using, withdrawing from the market or from service, or a decision obliging to implement FSCAs or to issue a safety note.

2. The President of the Office shall notify the European Commission and the competent bodies of Member States of issuing the decision referred to in Paragraph 1, and of the reasons behind it.

3. If the President of the Office decides that devices bearing the EC marking or custom-made devices which have been installed correctly, and maintained and used in line with their intended
purpose, may constitute a threat to life, health or safety of patients, users or other individuals, he/she shall issue an administrative decision on withdrawing them from the market and from service, or on banning or restricting placing them on the market or putting them into service.

4. The President of the Office shall promptly notify the European Commission of issuing the decision referred to in Paragraph 3, and of the reasons behind it, stating in the justification whether the inconsistency with the Act was a result of:

1) Failure to meet the essential requirements;
2) Incorrect use of harmonised norms in the declared scope;
3) Defects of the norms referred to in Subparagraph 2.

5. The President of the Office may announce the threats referred to in Paragraphs 1 and 3, adequately to the seriousness of the threat, also using mass media. The cost of such announcements shall be borne by the manufacturer, authorised representative, importer, or distributor of the device.

6. If, contrary to the provisions of the Act, the CE marking has been placed on the device or, contrary to the provisions of the Act, the CE marking has not been placed on the device, the President of the Office shall urge the manufacturer or the authorised representative to correct the negligence breaching the provisions of the Act within a specified time.

7. If the negligence is not corrected in a timely manner, the President of the Office shall issue an administrative decision on:

1) Withdrawing the device from the market;
2) Withdrawing the device from the market and from service;
3) Banning or restricting placing the device on the market or putting it into service.

8. If a product which is not a device is affixed the CE marking invoking the provisions of the Act, Paragraphs 6 and 7 shall apply accordingly.

Article 87.

If a product is mistakenly taken for a medical device, an active implantable medical device or an in vitro diagnostic medical device, or if a product is mistakenly not considered a device and:

1) The product is placed on the market or put into service in the territory of the Republic of Poland, or
2) The product’s manufacturer, authorised representative or importer responsible for placing the product on the market has the place of residence or the registered office on the territory of the Republic of Poland, or
3) A notified body authorised by the minister competent for health participated in the conformity assessment of the product,
- the President of the Office shall determine, by administrative decision, whether the product is a medical device, an active implantable medical device or an in vitro diagnostic medical device.

Article 88.

The President of the Office shall order, by administrative decision, to remove from the device, its packaging or instructions of use any markings or inscriptions which could be misleading as to the EC marking or the identification number of the notified body.

Article 89.

The decisions of the President of the Office referred to in Article 86(1), (3) and (7) shall be published in the official gazette – Public Information Bulletin and on the website of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, with a copy sent to the minister competent for health.
Chapter 11 Device use and maintenance

Article 90.

1. A device should be delivered properly, installed correctly, and maintained and used in accordance with its intended use. Device users must adhere to the instructions of use.

2. It shall be forbidden to launch and use a device with defects which may constitute risk to patients, users or other individuals.

3. The manufacturer, importer and distributor placing on the market in the territory of the Republic of Poland, or importing to the territory of the Republic of Poland with a view to putting into service in the territory, a device which, for its correct and safe operation requires special replacement parts, expendables or consumables defined by the device manufacturer, shall provide a list of suppliers of such parts or materials with the device.

4. The manufacturer, importer and distributor placing on the market in the territory of the Republic of Poland, or importing to the territory of the Republic of Poland with a view to putting into service in the territory, a device which, for its correct and safe operation requires professional installation, regular maintenance, regular or ad hoc service, software update, regular or ad hoc inspections, regulation, calibration, standardisations, checks or safety controls – which may not, according to the instructions of use, be performed by the user – shall provide a list of entities authorised by the manufacturer or the authorised representative to perform such actions with the device.

5. Entities included in the list referred to in Paragraph 4 shall:
   1) Have at their disposal the technical capacity, replacement parts, expendables and consumables determined by the manufacturer;
   2) Have the device service instructions that are understandable for the personnel as well as the relevant procedures and instructions for the actions referred to in Paragraph 4, determined by the manufacturer;
   3) Have personnel with the qualifications and professional experience determined by the manufacturer.

6. The service provider shall keep documentation of performed installations, repairs, maintenance, servicing, software updates, inspections, regulations, calibrations, standardisations, checks and safety controls of the device which is used to provide health care services, including in particular the dates of the activities, name of the person or the business name of the entity which performed them, their description, results and comments on the device.

7. The service provider shall keep documentation stating the dates of subsequent maintenance, servicing, inspections, regulations, calibrations, standardisations, checks and safety controls of the device which is used to provide health care services resulting from the instructions of use or recommendations of the entities which performed the activities referred to in Paragraph 6.

8. The service provider shall keep the documentation referred to in Paragraphs 6 and 7 for a period of at least five years since he/she ceases to use the device to provide health care services.

9. The service provider shall make the documentation referred to in Paragraphs 6 and 7 available to bodies and entities supervising the service provider or authorised to perform inspections.

10. If justified by the safety of patients, users and third persons, the minister competent for health may determine, by ordinance:
   1) The conditions of using and distributing devices, including requirements on user qualification;
   2) The conditions of performing the activities referred to in Paragraph 4, including the requirements for technical equipment of entities and qualifications of their personnel performing the activities;
- taking into account the health of patients, the safety of users and third persons, the intended use and function of devices, and the risk inherent in their use.

Chapter 12 Access to information

Article 91.
The provisions of the Act of 6 September 2001 on access to public information (Dz. U. No 112, item 1198, as amended⁹) shall not apply to the information obtained in connection with application of the Act, with the exception of the following:

1) Information in the database referred to in Article 64(1);
2) Information on the safety of devices provided to device recipients or users;
3) Information in conformity certificates.

Chapter 13 Penal provisions

Article 92.
1. Anyone who places on the market devices whose names, markings or instructions of use are misleading, as specified in Article 8(1), shall be subject to a fine, restriction of liberty or deprivation of liberty for up to two years.
2. Anyone who puts into service, distributes, delivers or makes available the devices referred to in Paragraph 1, shall be subject to a fine, restriction of liberty or deprivation of liberty for up to a year.
3. Anyone who disseminates information on devices which is misleading as specified in Article 8(1), shall be subject to a fine.

Article 93.
Anyone who, contrary to the obligation to perform device conformity assessment referred to in Article 13(1), allows placing a device on the market without the assessment, shall be subject to a fine, restriction of liberty or deprivation of liberty for up to two years.

Article 94.
Anyone who places on the market devices whose conformity certificates issued by notified bodies expired, were suspended or withdrawn, shall be subject to a fine, restriction of liberty or deprivation of liberty for up to a year.

Anyone who, contrary to Article 10(2), supplies or makes in vitro diagnostic devices other than the devices referred to in Article 2(1)(39)(b) and (c) or devices for self-control available to users other than professional users, shall be subject to the same punishment.

Article 95.
Anyone who places on the market systems or procedure packs or sterilises and places on the market systems, procedure packs or medical devices affixed the CE marking contrary to the

⁹ Amendments to the said Act were published in Dz. U. of 2002, No. 153, item 1271, of 2004, No. 240, item. 2407 and of 2005, No 64, item 565 and No. 132, item 1110.
requirements provided for in Article 30, shall be subject to a fine, restriction of liberty or deprivation of liberty for up to a year.

Article 96.

Anyone who supplies, makes available or distributes devices which do not meet the requirements of the Act shall be subject to a fine, restriction of liberty or deprivation of liberty for up to a year.

Article 97.

Anyone who places on the market, supplies or makes available a device contrary to Article 14 shall be subject to a fine.

Article 98.

Anyone who places on the market, puts into service, distributes, supplies or makes available a device after its expiry date or whose time of use or the number of safe uses set by the manufacturer was exceeded shall be subject to a fine.

Article 99.

1. Anyone who conducts a clinical investigation of a device without the relevant permit shall be subject to a fine, restriction of liberty or deprivation of liberty for up to two years.
2. Anyone who, contrary to the conditions set forth in Chapter 6, conducts a clinical investigation of a device while risking the life or health of subjects shall be subject to the same punishment.

Article 100.

Anyone who fails to make a report or notification referred to in Article 58 or fails to notify of a change in the data referred to in Article 61 shall be subject to a fine.

Article 101.

1. Anyone who prevents or makes it difficult for a person authorised by the President of the Office to conduct the control referred to in Article 57 shall be subject to a fine, restriction of liberty or deprivation of liberty for up to two years.
2. Anyone who prevents or makes it difficult for a person authorised by the President of the Office to conduct the control referred to in Article 69(1)(2) and (3) shall be subject to the same punishment.

Article 102.

1. Anyone who, contrary to the obligation referred to in Article 74(2) or (4), fails to report a medical incident shall be subject to a fine, restriction of liberty or deprivation of liberty for up to a year.
2. Anyone who, contrary to the obligation referred to in Article 18, fails to cooperate with the President of the Office or the authorised manufacturer or the entity or person authorised by the manufacturer to act on his/her behalf as concerns medical incidents or in matters concerning device safety or fails to inform the President of the Office on hazardous devices shall be subject to the same punishment.
3. Anyone who, contrary to the obligation referred to in Article 75(3), fails to cooperate and does not participate in FSCA implementation thus risking the life or health of patients, device users or third persons shall be subject to the same punishment.

**Article 103.**
Anyone who hinders explanatory proceedings on a medical incident by not providing information or not making the device available for examinations and assessment contrary to the provisions of Article 74(6), Article 76(2) and (3), Article 77, Article 78(1)-(7), Article 80(1) or Article 81(3) shall be subject to a fine.

**Chapter 14**
Amendments to regulations in force, transitional and final provisions

**Article 104.**

Article 4(1) of the Act of 20 July 1950 on the profession of a feldsher (Dz. U. of 2004 No 53, item 531 and No 210, item 2135 and of 2009 No 98, item 817) shall read as follows:

“1. A feldsher or a senior feldsher have the right to prescribe medicinal products which are authorised for trading in the territory of the Republic of Poland, with the exception of potent medicines and certain psychoactive and psychotropic substances, as well as medical devices, in vitro diagnostic medical devices, accessories of medical devices, accessories of in vitro diagnostic medical devices, within the meaning of the Act of 20 May 2010 on medical devices (Dz. U. No 107, item 679).”

**Article 105.**

Article 69b(3) and (4) of the Act of 21 November 1967 on the general duty of defence of the Republic of Poland (Dz. U. of 2004, No 241, item 2416, as amended10) shall read as follows:

“3. Soldiers performing compulsory military service, military training, and military exercises, candidates for professional soldiers and soldiers performing military service in the case of mobilization and at war are entitled to free supplies of medicinal products, medical devices and accessories of medical devices within the meaning of the Act of 20 May 2010 on medical devices (Dz. U. No 107, item 679) other than those marked with “Rp” (prescription only), financed from the state budget, in the part at the disposal of the Minister of National Defence.

4. The Minister of National Defence shall determine by ordinance, in consultation with the minister competent for health, a list of medicinal products marked with the “OTC” symbol and devices referred to in Paragraph 3 dispensed free of charge, along with the manner and procedure of financing their costs, taking into account the rules and manner of spending public funds.”

**Article 106.**

In Article 2a(1) of the Act of 19 April 1991 on pharmacists' chambers (Dz. U. of 2008 No 136, item 856):

1) Subparagraph 3 shall read as follows:

10 Amendments to the consolidated text of said Act were published in Dz.U. of 2004 No 277, item 2742, z 2005 No 180, item 1496, z 2006 No 104, item 708 and 711 and No 220, item 1600, z 2007 No 107, item 732 and No 176, item 1242, z 2008 No 171, item 1056, No 180, item 1109, No 206, item 1288, No 208, item 1308 and No 223, item 1458 and of 2009 No 22, item 120, No 97, item 801, No 161, item 1278, No 190, item 1474 and No 219, item 1706.

2010-10-05
“3) Dispensing medicinal products and medical devices, in vitro diagnostic medical devices, accessories of medical devices, accessories of in vitro diagnostic medical devices and active implantable medical devices within the meaning of the Act of 20 May on medical devices (Dz. U. No 107, item 679) traded in pharmacies, hospital pharmacy units and pharmaceutical wholesale companies;”

2) Sections 5 and 6 shall read as follows:

“5) Exercising supervision of manufacturing, trade, storage, use and disposal of medicinal products and the devices referred to in Subparagraph 3, including state reserves;

6) Providing information and advice on the effects and usage of medicinal products and the devices referred to in Subparagraph 3 traded in pharmacies and pharmaceutical wholesale companies;”.

Article 107.

The following amendments shall be introduced to the Act of 30 August 1991 on health care centres (Dz. U. of 2007, No 14, item 89, as amended):11

1) Article 9(4) shall read as follows:

“4. Health care centres shall purchase medical devices, accessories of medical devices, in vitro diagnostic medical devices, accessories of in vitro diagnostic medical devices, active implantable medical devices as well as systems and procedure packs and apply them in accordance with the requirements of the Act of 20 May 2010 on medical devices (Dz. U. No 107, item 679).”;

2) Article 20(1)(2) shall read as follows:

“2) Medicinal products and medical devices, accessories of medical devices, in vitro diagnostic medical devices, accessories of in vitro diagnostic medical devices and active implantable medical devices, within the meaning of the Act of 20 May 2010 on medical devices;”

3) Article 32c shall read as follows:

“Article 32c. 1. A nursing home shall provide 24-hour in-patient services which include nursing and rehabilitation of persons who do not require hospitalisation, and shall provide them with medicinal products and medical devices, accessories of medical devices, in vitro diagnostic medical devices, accessories of in vitro diagnostic medical devices within the meaning of the Act of 20 May 2010 on medical devices, accommodation and board appropriate for their health and care during cultural and leisure activities.

2. The insured and other persons eligible to free health care services pursuant to separate regulations, staying in a nursing home which is a public health care centre, are provided with medicinal products, medical devices, accessories of medical devices, in vitro diagnostic medical devices and accessories of in vitro diagnostic medical devices within the meaning of the Act of 20 May 2010 on medical devices, as decided by the nursing home's physician.”;

4) Article 65(1)(1)(c) shall read as follows:

“c) Verification of adherence to requirements concerning the authorisation of use, the manner of use, and the maintenance when providing health care services of medical devices, accessories of medical devices, in vitro diagnostic medical devices, accessories of in vitro diagnostic medical devices, and active implantable medical devices within the meaning of the Act of 20 May 2010 on medical devices, and ambulances.”

11 Amendments to the consolidated text of said Act were published in Dz.U. of 2007 No 123, item 849, No 166, item 1172, No 176, item 1240 and No 181, item 1290, z 2008 No 171, item 1056 and No 234, item 1570, z 2009 No 19, item 100, No 76, item 641, No 98, item 817, No 157, item 1241 and No 219, item 1707 and of 2010 No 96, item 620.
Article 108.

Article 8(1)(2a) of the Act of 3 April 1993 – Hallmarking Law (Dz.U. No 55, item 249, as amended\(^{12}\)) shall read as follows:

“2a) medical devices, in vitro diagnostic medical devices, accessories of medical devices, accessories of in vitro diagnostic medical devices, and active implantable medical devices within the meaning of the Act of 20 May 2010 on medical devices (Dz.U. No 107, item. 679), or parts thereof,”

Article 109.

Act of 19 August 1994 on the protection of mental health (Dz.U. No 111, item 535, as amended\(^{13}\)) shall be amended as follows:

1) Article 10(2) and (3) shall read as follows:

“2. The persons referred to in Article 3(1)(a) and (b), staying at the psychiatric hospital, shall also have the right to medicinal products, medical devices, in vitro diagnostic medical devices, accessories of medical devices, accessories of in vitro diagnostic medical devices, and active implantable medical devices, within the meaning of the Act of 20 May 2010 on medical devices (Dz.U. No 107, item. 679), and auxiliary appliances, for which no fees shall be charged from those persons.

3. The persons referred to in Article 3(1)(a) and (b) shall also have the right to medicinal products and medical devices, in vitro diagnostic medical devices, accessories of medical devices, accessories of in vitro diagnostic medical devices, and active implantable medical devices, within the meaning of the Act of 20 May 2010 on medical devices, in line with the rules specified in Article 37 of the Act on benefits.”;

2) Article 10c(2)(3) and (4) shall read as follows:

“3) the owner or an employee of a pharmacy, a pharmaceutical wholesale company or the manufacturer of a medicinal product or of a medical device, in vitro medical device, accessory of a medical device, accessory of an in vitro diagnostic medical device and an active implantable medical device, within the meaning of the Act of 20 May 2010 on medical devices;

4) the owner of shares in a company running a health care centre, a pharmacy or a pharmaceutical wholesale outlet, or manufacturing medicinal products or medical devices, in vitro diagnostic medical devices, accessories of medical devices, accessories of in vitro diagnostic medical devices and active implantable medical devices, within the meaning of the Act of 20 May 2010 on medical devices.”

Article 110.

Act of 30 May 1996 on the state reserve (Dz.U. of 2007, No 89, item 594 and of 2008, No 227, item 1505) shall be amended as follows:

1) Article 1(1) shall read as follows:

“1) creation and management of the state reserve of commodities, materials, fuels, machines, devices, agricultural products and semi-finished food products, medicinal products and medical

\(^{12}\) Amendments to the said Act were published in Dz.U. of 2000, No 120, item 1286 and of 2001 No 63, item 636, No 126, item 1382 and No 154, item 1800 and of 2003, No 171, item 1664.

\(^{13}\) Amendments to the said Act were published in Dz.U. of 1997, No 88, item 554 and No 113, item 731, of 1998, No 106, item 668, of 1999, No 11, item 95, of 2000, No 120, item 1268, of 2005, No 141, item 1183 and No 167, item 1398 and No 175, item 1462, of 2007, No 112, item 766 and No 121, item 831, of 2008, No 180, item 1108 and of 2009, No 76, item 641 and No 98, item 817.
devices, in vitro diagnostic medical devices, accessories of medical devices, accessories of in vitro diagnostic medical devices and active implantable medical devices, within the meaning of the Act of 20 May 2010 on medical devices (Dz.U. No 107, item 679), as well as other devices necessary to carry out the tasks related to defence and security of the state;”

2) Article 2(1) shall read as follows:

“1. The state reserve of commodities, materials, fuels, machines, devices, agricultural products and semi-finished food products, medicinal products and medical devices, in vitro diagnostic medical devices, accessories of medical devices, accessories of in vitro diagnostic medical devices and active implantable medical devices, within the meaning of the Act of 20 May 2010 on medical devices, as well as other devices necessary to carry out the tasks related to defence and security of the state, shall hereby be created.”;

3) Article 3(1)(2) shall read as follows:

“2) The economic reserve intended in particular for meeting the basic needs of national economy in terms of commodities, materials and fuels, and for maintaining the continued provision of basic agricultural products, food products and semi-finished products, medicinal products and medical devices, in vitro diagnostic medical devices, accessories of medical devices, accessories of in vitro diagnostic medical devices, and active implantable medical devices, within the meaning of the Act of 20 May 2010 on medical devices, to the population of the country, within the periods specified in Subparagraph 1, and for eliminating or mitigating the distortions in the functioning of the national economy resulting from unforeseeable events and circumstances as well as from natural disasters.”;

4) Article 4(2)(2) shall read as follows:

“2) medicinal products and medical devices, in vitro diagnostic medical devices, accessories of medical devices, accessories of in vitro diagnostic medical devices, and active implantable medical devices within the meaning of the Act of 20 May 2010 on medical devices, in consultation with the minister competent for health;”;

5) Article 10(3)(1)(b) shall read as follows:

“b) medicinal products and medical devices, in vitro diagnostic medical devices, accessories of medical devices, accessories of in vitro diagnostic medical devices, and active implantable medical devices within the meaning of the Act of 20 May 2010 on medical devices,”

Article 111.

Act of 5 December 1996 on the profession of a physician and a dentist (Dz.U. of 2008 No 136, item 857, as amended) shall be amended as follows:

1) In Article 45:

a) Paragraph 1 shall read as follows:

14 Amendments to the consolidated text of the said Act were published in Dz. U. of 2009, No 6, item 33, No 22, item 120, No 40, item 323, No 76, item 641 and No 219, item 1706 and 1708 and of 2010 No 81, item 531.
“1. A physician may prescribe medicinal products authorised for marketing in the Republic of Poland on conditions specified in separate regulations, as well as medical devices, accessories of medical devices, in vitro diagnostic medical devices, accessories of in vitro diagnostic medical devices, and active implantable medical devices within the meaning of the Act of 20 May 2010 on medical devices (Dz.U. No 107, item 679).”

b) Paragraph 2 shall read as follows:

“2. In justified cases, a physician may prescribe medicinal products authorised for marketing in other countries, with a detailed justification in the medical documentation.”

2) Article 45b shall be repealed;

3) Paragraph 46 shall read as follows:


2. Paragraph 1 shall not apply if the physician administers to the patient, on an ad hoc basis, a medicinal product, medical device, accessory of medical device, in vitro diagnostic medical device, accessory of in vitro diagnostic medical device or active implantable medical device, within the meaning of the Act of 20 May 2010 on medical devices, in relation to help in emergency.

3. Paragraph 1 shall not apply to the custom-made devices referred to in Article 2(1)(42) of the Act of 20 May 2010 on medical devices.”

Article 112.

Article 33(1)(2) of the Act of 4 September 1997 on government administration sections (Dz.U. of 2007, No 65, item 437, as amended15) shall read as follows:

“2) supervision over medicinal products, medical devices, in vitro diagnostic medical devices, accessories of medical devices, accessories of in vitro diagnostic medical devices, active implantable medical devices, biocidal products as well as over cosmetics with regard to human safety and health;”

Article 113.

Article 4(1)(7) of the Act of 29 November 2000 – Atomic Law (Dz.U. of 2007, No 42, item 276, as amended16) shall read as follows:

“7) intentional addition of radioactive substances in the production process of consumer products and medical devices, in vitro diagnostic medical devices, accessories of medical devices, accessories of in vitro diagnostic medical devices, and active implantable medical devices, within the meaning of the Act of 20 May 2010 on medical devices (Dz.U. No 107, item 679), trade in such devices and the import of such devices and consumer products, to which the radioactive substances were added, to the territory of the Republic of Poland and their export therefrom.”

15 Amendments to the consolidated text of said Act were published in Dz.U. of 2007 No 107, item 732 and No 120, item 818 and No 173, item 1218, of 2008, No 63, item 394 and No 199, item 1227, No 201, item 1237, No 216, item 1370 and No 227, item 1505; of 2009, No 42, item 337, No 68, item 574, No 77, item 649, No 157, item 1241, No 161, item 1277, No 168, item 1323 and No 201, item 1540, and of 2010, No 28, item 143 and 146.

16 Amendments to the consolidated text of the said Act were published in Dz. U. of 2008, No 93, item 583 and No 227, item 1505, and of 2009, No 18, item 97 and No 168, item 1323.
Article 114.

Article 1(4)(3)(f) of the Act of 11 January 2001 on chemical substances and preparations (Dz.U. of 2009, No 152, item 1222) shall read as follows:

“f) Invasive medical devices or medical devices intended for application in direct contact with human body, within the meaning of the Act of 20 May 2010 on medical devices (Dz.U. No 107, item 679), if the provisions of the said Act or the regulations issued pursuant to the Act specify their classification and labelling ensuring the degree of information and protection of man and environment equivalent to the one provided for in this Act, excluding Article 33 and 33b, Article 34f-34j, Article 35(2), Article 37a and 37b, Article 37h-37l and Article 39, and the regulations issued pursuant to Article 31.”

Article 115.

Paragraph 3 shall be added in Article 1 of the Act of 30 March 2001 on cosmetics (Dz.U. No 42, item 473, as amended17), and shall read as follows:

“3. The Act shall not apply to medical devices and accessories of medical devices, in vitro diagnostic medical devices and accessories of in vitro diagnostic medical devices, and active implantable medical devices within the meaning of the Act of 20 May 2010 on medical devices (Dz. U. No 107, item. 679).”

Article 116.

Article 2(3) of the Act of 11 May 2001 – Law on Measures (Dz.U. of 2004, No 243, item 2441, as amended18) shall be repealed.

Article 117.

In Article 3(1)(10) of the Act of 5 July 2001 on prices (Dz.U. No 97, item 1050, as amended19) the full stop shall be replaced by a comma, and Subparagraph 11 shall be added reading as follows:

“11) Medical devices - medical devices, in vitro diagnostic medical devices, accessories of medical devices, accessories of in vitro diagnostic medical devices, and active implantable medical devices, within the meaning of the Act of 20 May 2010 on medical devices (Dz.U. No 107, item 679).”

Article 118.

The Act of 27 July 2001 on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Dz.U. No 126, item 1379, as amended20) shall be amended as follows: 1) Introductory sentence in Article 3(4) shall read as follows:

“Shall have knowledge of the Polish law and the EU law in respect of medicinal products and biocidal products, medical devices, accessories of medical devices, in vitro diagnostic medical devices, accessories of in vitro diagnostic medical devices, active implantable medical devices, systems and procedure packs within the meaning of the Act of 20 May 2010 on medical devices (Dz.U. No 107, item 679), and at least three years of employment as a manager in.”

2) Article 5a(1) shall read as follows:

17 Amendments to the said Act were published in Dz.U. of 2003, No 73, item 659, No 189, item 1852 and No 208, item 219, of 2004, No 213, item 2158 and of 2009, No 18, item 97, No 20, item 106 and No 91, item 740.
18 Amendments to the consolidated text of said Act were published in Dz.U. of 2005 No 163, item 1362 and No 180, item 1494, of 2006, No 170, item 1217, and No 249, item 1834, of 2007, No 176, item 1238, of 2008, No 227, item 1505, of 2009, No 18, item 97 and No 91, item 740, and of 2010, No 66, item 421.
19 Amendments to the said Act were published in Dz.U. of 2002 No 144, item 1204, of 2003 No 137, item 1302, of 2004 No 96, item 959 and No 210, item 2135, of 2007 No 176, item 1172, of 2008 No 157, item 976 and of 2009 No 118, item 989.
20 Amendments to the said Act were published in Dz.U. of 2002 No 152, item 1263, of 2004 No 93, item 896, of 2006 No 170, item 1217 and of 2007, No 75, item 492 and of 2008, No 227, item 1505.
1. The President of the Office shall issue decisions in respect of medical devices, accessories of medical devices, in vitro diagnostic medical devices, active implantable medical devices, systems and procedure packs specified in the Act of 20 May 2010 on medical devices”.

3) Article 5b shall read as follows:

“Article 5b. The competence of the President of the Office in respect of medical devices, accessories of medical devices, in vitro diagnostic medical devices, active implantable medical devices, systems and procedure packs within the meaning of the Act of 20 May 2010 on medical devices shall include in particular the following:

1) Maintaining a database of applications and notifications of medical devices, accessories of medical devices, in vitro diagnostic medical devices, active implantable medical devices, systems and procedure packs within the meaning of the Act of 20 May 2010 on medical devices;

2) Making entries of clinical investigations to the Central Register of Clinical Trials;

3) Control of clinical investigations;

4) Supervision of medical devices, accessories of medical devices, in vitro diagnostic medical devices, active implantable medical devices, systems and procedure packs within the meaning of the Act of 20 May 2010 on medical devices manufactured or placed on the market and put into service on the territory of the Republic of Poland;

5) Supervision of medical incidents and measures in the area of safety of medical devices, accessories of medical devices, in vitro diagnostic medical devices, active implantable medical devices, systems and procedure packs within the meaning of the Act of 20 May 2010 on medical devices;

6) Settlement of disputes concerning the classification of medical devices and qualification of in vitro diagnostic medical devices;


8) Issuing Free Sales Certificates;

9) Cooperation with competent authorities of the Member States of the European Union and of the countries of the European Free Trade Area (EFTA) – parties to the Agreement on the European Economic Area;

10) Cooperation and exchange of information with international organisations, including exchange of information in the area of security.”

4) Article 6(2) shall be repealed;

5) Article 7(3) shall read as follows:


Article 119.
Act of 6 September 2001 – Pharmaceutical Law (Dz.U. of 2008, No 45, item 271, as amended\textsuperscript{21}) shall be amended as follows:

1) After Article 2, Article 2a shall be added which shall read as follows:

“Article 2a. Whenever this Act refers to a medical device, it shall mean a medical device, in vitro diagnostic medical device, accessory of medical device, accessory of in vitro diagnostic medical device and active implantable medical device, within the meaning of the Act of 20 May 2010 (Dz.U No 107, item 679), unless stated otherwise in this Act.”

2) Article 3a shall read as follows:

“Article 3a. The Act shall apply to the product meeting the criteria of a medicinal product as well as the criteria of another type of product, in particular, a dietary supplement, cosmetic or a medical device, specified in other regulations.”

3) Article 121(3) shall read as follows:

“3. In case of a justified suspicion that a medical device does not meet the relevant requirements, the voivodeship pharmaceutical inspector shall promptly notify the President of the Office and the Main Pharmaceutical Inspector about it, shall secure the device against its further placing on the market and putting into service on conditions specified for medicinal products, and shall make available a sample of the secured device for testing and analysis by the manufacturer, authorised representative and other entities or persons authorised by the manufacturer to act on his/her behalf in medical incidents and in cases concerning safety of the device.”

\textbf{Article 120.}

Article 1(2) of the Act of 30 August 2002 on the conformity assessment system (Dz.U. of 2004 No 204, item 2087, as amended\textsuperscript{22}) shall read as follows:


\textbf{Article 121.}

Article 2(7) of the Act of 13 September 2002 on biocidal products (Dz.U. of 2007 No 39, item 252, of 2008 No 171, item 1056) and of 2009 No 20, item 106) shall read as follows:


\textbf{Article 122.}

Act of 11 September 2003 on the military service of professional soldiers (Dz.U. of 2010, No 90, item 593) shall be amended as follows:

1) Article 24(7)(2) shall read as follows:

\textsuperscript{21} Amendments to the consolidated text of said Act were published in Dz.U. of 2008 No 227, item 1505 and No 234, item 1570, of 2009, No 18, item 97, No 31, item 206, No 92, item 753, No 95, item 788; and No 98, item 817, and of 2010, No 78, item 513.

\textsuperscript{22} Amendments to the consolidated text of said Act were published in Dz.U. of 2005 No 64, item 565, and No 267, item 2258, of 2006, No 170, item 1217, No 235, item 1700 and No 249, item 1832 and 1834, of 2007, No 21, item 124, and No 192, item 1381, of 2008, No 157, item 976, and No 227, item 1505 and of 2009, No 18, item 97.
“2) free of charge health care services and free of charge provision of medicinal products, medical devices and accessories of medical devices, within the meaning of the Act of 20 May 2010 on medical devices (Dz.U. No 107, item 670), being orthopaedic appliances and auxiliary appliances;”

2) Article 67(3) shall read as follows:

“3. Professional soldiers during training on the training grounds and during military exercises (cruises and flights) shall be entitled to free of charge health care services and free of charge provision of medicinal products included on the lists of basic and complementary drugs and compounded drugs, as well as medicinal products labelled as OTC and medical devices and accessories of medical devices, within the meaning of Act of 20 May 2010 on medical devices, specified in the regulations issued pursuant to Article 69b(4) of the Act of 21 November 1967 on the general duty of defence of the Republic of Poland.”.

Article 123.

Item 106 in Annex 3 to the Act of 11 March 2004 on the goods and services tax (Dz.U. No 54, item 535, as amended23) shall read as follows:

“106 – Regardless of the symbol of the Polish Classification of Products and Services Medical (PKWiU) - Medical devices, accessories of medical devices, in vitro diagnostic medical devices, accessories of in vitro diagnostic medical devices and active implantable medical devices, within the meaning of the Act of 20 May 2010 on medical devices (Dz.U. No 107, item 679), other than listed under other items of the Annex.”

Article 124.

Paragraph 4 shall be added o Article 20 of the Act of 2 July 2004 on the freedom of economic activity (Dz.U. of 2007, No 155, item 1095, as amended24), reading as follows:

“4. Paragraph 1 shall not apply to devices within the meaning of the Act of 20 May 2010 on medical devices (Dz.U. No 107, item 679).”

Article 125.

In Article 5(45) of the Act of 27 August 2004 on health care services financed from public funds (Dz.U. of 2008 No 164, item 1027, as amended25) the full stop shall be replaced by a semicolon, and Subparagraph 46 shall be added, reading as follows:

“(46) Medical devices – medical devices, in vitro diagnostic medical devices, accessories of medical devices, accessories of in vitro diagnostic medical devices and active implantable medical devices, within the meaning of the Act of 20 May 2010 on medical devices (Dz.U. No 107, item 679).”

23 Amendments to the said Act were published in Dz.U. of 2005 No 14, item 113, No 90, item 756, No 143, item 1199 and No 179, item 1484, of 2006 No 143, item 1028 and 1029, of 2007 No 168, item 1187 and No 192, item 1382, of 2008 No 74, item 444, No 130, item 826, No 141, item 888 and No 209, item 1320, of 2009 No 3, item 11, No 116, item 979, No 195, item 1504, No 201, item 1540 and No 215, item 1666 and of 2010 No 57, item 357 and No 75, item 473.

24 Amendments to the consolidated text of the said Act were published in Dz.U. of 2007, No 180, item 1280, of 2008, No 70, item 416, No 116, item 732, No 141, item 888, No 171, item 1056 and No 216, item 1677, of 2009, No 3, item 11, No 18, item 97, No 168, item 1323 and No 201, item 1540 and of 2010, No 47, item 278.

25 Amendments to the consolidated text of the said Act were published in Dz.U. of 2008 No 216, item 1367, No 225, item 1486, No 227, item 1505, No 234, item 1570 and No 237, item 1654, of 2009 No 6, item 33, No 22, item 120, No 26, item 157, No 38, item 299, No 92, item 753, No 97, item 800, No 98, item 817, No 111, item 918, No 118, item 989, No 157, item 1241, No 161, item 1278 and No 178, item 1374 and of 2010 No 50, item 301.

2010-10-05
Article 126.

Article 3(7) of the Act of 8 September 2006 on State Emergency Medical Services (Dz.U. No 191, item 1410, as amended\(^26\)) shall read as follows:

“7) First aid – a group of activities undertaken in order to save the life of a person whose health is under threat, performed by a person at the site of the incident, also with the use of medical devices and accessories of medical devices within the meaning of the Act of 20 May 2010 on medical devices (Dz.U. No 107, item 679), as well as medicinal products administered without the doctor's prescription, which are authorised for marketing on the territory of the Republic of Poland.”

Article 127.

Paragraph 35(3) in Column 2 of Part III of the Annex to the Act of 16 November 2006 on stamp duty (Dz.U. No 225, item 1635, as amended\(^27\)) shall read as follows:

“3) for manufacturing and processing of nuclear materials, radioactive sources and waste, spent nuclear fuel, isotopic enrichment, and for producing devices containing radioactive sources, as well as for intentional addition of radioactive substances in the production process of consumer products and of medical devices, in vitro diagnostic medical devices, accessories of medical devices, accessories of in vitro diagnostic medical devices, and active implantable medical devices, for trade in those devices and for transport on and export from the territory of the Republic of Poland of consumer products, medical devices, in vitro diagnostic medical devices, accessories of medical devices, accessories of in vitro diagnostic medical devices, and active implantable medical devices, to which radioactive substances were added, and for construction, start-up, operation (test or permanent) and for closure or liquidation of nuclear facilities, radioactive waste storage facilities, bunkers and spent nuclear fuel storage facilities.”

Article 128.

Article 5(5) of the Act of 13 April 2007 on electromagnetic compatibility (Dz.U. No 82, item 556) shall read as follows:

“5) Medical devices, accessories of medical devices, in vitro diagnostic medical devices, accessories of in vitro diagnostic medical devices, and active implantable medical devices, within the meaning of the Act of 20 May 2010 on medical devices (Dz.U. No 107, item 679);”

Article 129.

In Article 10(1) of the Act of 6 November 2008 on health care consultants (Dz.U. of 2009, No 52, item 419 and No 76, item 641):

1) Subparagraph 4a shall be added after Subparagraph 4, and it shall read as follows:

“4a) Notifying the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products on revealed medical incidents or irregularities concerning medical devices, accessories of medical devices, in vitro diagnostic medical devices, accessories of in vitro diagnostic medical devices, active implantable medical devices, and systems and

\(^{26}\) Amendments to the said Act were published in Dz.U. of 2007 r. No 89, item 590 and No 166, item 1172, of 2008 No 17, item 101 and No 237, item 1653 and of 2009 No 11, item 59 and No 122, item 1007.

\(^{27}\) Amendments to the said Act were published in Dz.U. of 2007 No 64, item 427, No 124, item 859 and No 128, item 883, of 2008 No 44, item 262, No 63, item 394, No 182, item 1121, No 195, item 1198, No 216, item 1367 and No 220, item 1414, of 2009 No 6, item 33, No 22, item 120, No 57, item 466, No 72, item 619 and of 2010 No 8, item 51 and No 81, item 531.
procedure packs, within the meaning of the Act of 20 May 2010 on medical devices (Dz.U. No 107, item 679);

2) Subparagraph 6a shall be added after Subparagraph 6, reading as follows:

“6a) Issuing opinions on medical devices, accessories of medical devices, in vitro diagnostic medical devices, accessories of in vitro diagnostic medical devices and active implantable medical devices, within the meaning of the Act of 20 May 2010 on medical devices, at the request of the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products;”

Article 130.

Act of 5 December 2008 on the prevention and control of infections and communicable diseases in humans (Dz.U No 234, item 1570 and of 2009 No 76, item 641) shall be amended as follows:

1) Article 11(2)(3)(b) shall read as follows:

“b) Medical devices, in vitro diagnostic medical devices, accessories of medical devices, accessories of in vitro diagnostic medical devices and active implantable medical devices, within the meaning of the Act of 20 May 2010 on medical devices (Dz.U. No 107, item 679), and surfaces of premises and devices;”

2) Article 42(2)(3) shall read as follows:

“3) Storage of provisions of medicinal products and medical devices, in vitro diagnostic medical devices, accessories of medical devices, accessories of in vitro diagnostic medical devices, and active implantable medical devices, within the meaning of the Act of 20 May 2010 on medical devices, and other necessary devices and equipment in the amount ensuring the provision of health care services referred to in Subparagraphs 1 and 2 for at least 3 days;”

Article 131.

Article 1(2) of the Act of 7 May 2009 on packaged goods (Dz.U. No 191, item 740) shall read as follows:

“2. The Act shall apply to medical devices, accessories of medical devices, in vitro diagnostic medical devices, accessories of in vitro diagnostic medical devices and active implantable medical devices, within the meaning of the Act of 20 May 2010 on medical devices (Dz.U. No 107, item 679), and to medicinal products and biocidal products within the scope in which it does not infringe other regulations concerning those products.”

Article 132.

Whenever separate regulations refer to medical devices, it shall mean medical devices, active implantable medical devices, in vitro diagnostic medical devices, accessories of medical devices, accessories of in vitro diagnostic medical devices, systems and procedure packs consisting of medical devices.

Article 133.

1. The obligation stemming from Article 58, within 12 months from the entry into force of the Act, shall not apply to the devices entered to the register of medical devices and of authorisation holders responsible for placing them on the market and putting them into use kept pursuant to the previous regulations.
2. The data on the device subject to the entry into the register referred to in Paragraph 1 shall be transferred to the database referred to in Article 64(1), at the request of the entity referred to in Article 58.

3. The request for the data transfer shall include:
   1) Name and address of the entity filing the request;
   2) Trade name of the device;
   3) Name and address of the manufacturer.

4. The request for the data transfer shall be submitted within 6 months from the entry into force of the Act.

5. The request for the data transfer shall not be subject to a fee.

6. If the request is incomplete or if the President of the Office does not have all the data referred to in Article 59, the President of the Office shall call on the entity to complete the request or data, setting the deadline at no less than 7 days from the receipt of the call; otherwise the request shall not be considered.

7. If the request or the data are not submitted, the data shall not be transferred.

8. If the data cannot be transferred, and after ineffective expiry of the deadline referred to in Paragraph 6, the President of the Office shall notify the entity which submitted the request that the request has not been examined.

9. In the case referred to in Paragraph 8, the entity which submitted the request shall perform the obligation referred to in Article 58 within 30 days from receiving the notification from the President of the Office.

10. The obligation stemming from Article 58 shall not apply to the device whose data have been transferred to the database referred to in Article 64(1).

Article 134.

The entities referred to in Article 58(3), which, before the day of the entry into force of the Act, had imported to the territory of the Republic of Poland the devices not subject to the obligatory entry to the register referred to in Article 133(1) and which, within 5 months from the day of the entry into force of the Act, import such devices to the territory of the Republic of Poland, shall notify about those devices within 6 months from the day of the entry into force of the Act.

Article 135.

Before the appointment of the authorised representative, the importer or the marketing authorisation holder shall be responsible for the device placed on the market at the responsibility of the importer or the marketing authorisation holder. The entities shall also keep the documentation referred to in Article 17(4) and Article 18(3)(2) and (3).

Article 136.

By 30 April 2011, the manufacturer or his/her authorised representative having the place of residence or the registered office on the territory of the Republic of Poland shall submit a copy of the notification referred to in Article 58(1) and concerning an in vitro diagnostic medical device to the competent authorities of the Member States on whose territory he/she places the product on the market.

Article 137.
The previously binging regulations shall apply to proceedings concerning clinical investigations, which have started and have not finished before the entry into force of the Act.

**Article 138.**

The devices placed on the market before the day of the entry into force of the Act, which meet the requirements specified in the Act referred to in Article 140, may remain on the market and be put into service after that date.

**Article 139.**

The implementing regulation issued pursuant to Article 69b(4) of the Act referred to in Article 105 shall remain in force until the day of entry into force of the implementing regulation issued pursuant to Article 69b(4) of the Act referred to in Article 105, in the wording from this Act, but not longer than until 21 March 2011.

**Article 140.**

The Act of 20 April 2004 on medical devices (Dz.U. No 93, item 896, of 2005 No 64, item 565, of 2007 No 176, item 1238 and of 2008 No 157, item 976) shall expire.

**Article 141.**

The Act shall enter into force 3 months after its publication, except for:

1) Article 90(3)-(5) which shall enter into force 12 months after the day of the entry into force of the Act;
2) Article 48(2), Article 64(2) and Article 83(1)(2) which shall enter into force on 1 May 2011.