ON MEDICAL DEVICES IN THE REPUBLIC OF ALBANIA

In accordance with Article 81, Clause 1 of the Constitution of the Republic of Albania, with the proposal of the Council of Ministers

THE ASSEMBLY
OF THE REPUBLIC OF ALBANIA

DECIDED:

CHAPTER I
GENERAL PROVISIONS

Article 1
Scope

This law is intended to provide a high level of safety and health protection towards the patients, users and third parties, as well as to preserve the levels of effectiveness of medical devices provided by the manufacturer.

Article 2
Field of application

1. This law provides for requirements on:
   
a. Medical devices and accessories (hereinafter referred to as medical devices) and their production;
   b. Launching medical devices and their implementation on the market;
   c. Provision of clinical assessments on medical devices;
   d. Professional users of medical devices.

2. This law is not applicable for users, manufacturers, the launch and the availability of the following products:
   
a. Cosmetic products;
   b. Personal protective equipment;
   c. Transplant of tissue or cells of human origin and products incorporated
or derived from tissue or cells of human origin;

c. Transplant of tissue or cells of animal origin, other than products manufactured from lifeless or rendered lifeless animal tissue;

e. Medical devices of in vitro diagnostics.

**Article 3**

**Definitions**

1. “*medical device*” is any instrument, apparatus, material or any other means, utilised either alone or combined, also including the required program for the accurate use and with the primary purpose of the manufacturer regarding human waste and with the purpose of:

   - diagnostics, prevention, monitoring, treatment or soothing of the illness,
   - diagnostics, monitoring, treatment or soothing or compensation of an injury or disability,
   - investigation, replacement or modification of the anatomy or the physiological process,
   - control of conception

   and those that cannot be used according to the primary purpose on the human body by pharmacological, immunological or metabolic means, but that may be aided to function by such means;

2. “*Accessory*” is a means which, when not classified as a device, is intended to be used by the manufacturer as an attachment to a device that enables it to function in accordance with the device usage from the device manufacturer;

3. “*Actively implanted medical device*” is a medical device that, in order to function, is supported by an electrical power source or a power source other than the one produced directly from the human body, or gravity, and that is partially or completely inserted inside the human body by surgical means or not, or by a non-surgical intervention inside a natural gap, and is intended to stay there following the procedure;

4. “*In vitro diagnostic medical device*” is any medical device that is a reagent, reactive, calibrating product, control material, tool, instrument, apparatus, means or system, used either alone or combined, intended to be used in vitro by the manufacturer for the examination of the samples, including the donation of blood and tissue taken from the human body, intended solely or mainly for the provision of information regarding:
   — physiological or pathological condition, or
   — congenital abnormality, or
   — to establish safety and compatibility with possible receivers, or
   — to monitor therapeutic measures.
Sample receivers are considered to be in vitro diagnostic medical devices. ‘Sample receivers’ are such devices, either of the vacuum type or not, which are produced by the manufacturer with the only scope of keeping and preserving samples taken from the human body intended for in vitro diagnostic examinations.

Products for general laboratory use are not in vitro diagnostic medical products, unless these products, depending on their characteristics, are produced by the manufacturer for the only intended use of in vitro diagnostic examination;

5. “ordered device” is any device manufactured in accordance with the written order of a qualified physician, who gives, within the realm of his responsibilities, specific manufacturing characteristics and is intended to be used on a particular person. The aforementioned order may also be released by other authorized persons, based on his qualifications to do so. Mass produced devices that need to adapt in order to meet the specific requirements of the physician or any other professional user, are not considered to be ordered devices;

6. “device that is subject to clinical investigation” is a medical device that is clinically investigated by a professional user;

7. “User of medical devices” is one who uses the medical device without the supervision of a health care provider, who is termed ordinary user of medical devices, or a person who uses a medical device to obtain clinical facts in the process of providing health care service and in studies, science or research, termed a professional user;

8. “intended use of the medical device” is the intended use of the device, in accordance with the data presented by the manufacturer on labelling, in the instructions and/or promotional materials;

9. “The launch” is making a device available for the first time, by payment or not, other than a device designed for clinical investigation, intended to be delivered and/or used in the local market, regardless if it is new or completely reconditioned;

10. “availability” is the stage at which a device is made available to the end user, being ready for use for the first time in the local market for its intended purpose;

11. “authorized representative” is any natural or legal person, established within the territory of the Republic of Albania which, clearly designated by the manufacturer, acts in the name and on behalf of the manufacturer. Country National authorities and organizations communicate with the authorised representative instead of the manufacturer regarding the rights of the aforementioned;

12. “Undesirable event” with the medical device is an accident and/or incident that causes or has the potential to cause unexpected or undesirable effects concerning the safety of patients, users or other persons that occur whilst using the medical device.

CHAPTER II
THE PRODUCTION AND LAUNCH OF THE DEVICE

Article 4
Responsibility of the Manufacturer

1. The manufacturer is responsible for designing, manufacturing, packaging and labelling of a medical device, regardless of whether these actions are performed by this person himself or in his name by a third party.
2. The obligations of this law that must be met by the manufacturers also serve for the person who collects, packages, processes, fully reconditions or labels one or more finished products, or assigns them for their designated purpose as a device, with the scope of launching it under his name.
3. The first paragraph of this article is not applicable to the person who assembles or adapts devices that are already on the market for their intended purpose for a specific patient.

Article 5
Launch and Availability

1. The medical devices will be launched and/or made available only if they meet the stated requirements in this Law, when they are properly equipped, installed, maintained and used in accordance with their designated purpose.
2. The Minister of Health determines the conditions and the procedure for the notification of introducing the medical devices on the market and for performing important modifications to medical devices.

Article 6
Requirements for the Launch and Availability of Medical Devices

1. A medical device is launched and is made available only if:
   a. the device meets the requirements of this law and regulations in its application;
   b. clinical assessment is provided for this device and if necessary, clinical investigation of the device has been performed;
   c. conformity assessment of the device has been performed;
   d. the device is accompanied by the appropriate information, necessary to the identification of the manufacturer and for the safe use of the device for the intended purpose.

2. The Minister of Health has the right, if an explicit request for this purpose has already been proposed, to allow the launch and the use of specific medical devices, the conformity of which has not been assessed, under the condition that the use of such devices is absolutely necessary for public health protection.
3. The medical devices that emit ionizing radiation, besides the requirements of this law, should also meet the requirement of Law No. 7870, date 13/10/1994 “On ionizing radiation”, as amended.

4. When a medical device within its structure has, as an inseparable part, a material which if used separately, may be called a medical product, in addition to the requirements of this law, requirements of other acts for the medical products are also applicable.

5. In order to guarantee the safety of gas pipes that provide medical gas to health care services, in addition to the requirements of this law, requirements of other acts for the safety of devices under pressure also apply.

6. The basic information regarding the safe use of a medical device for the intended purpose, that accompanies a medical device that will be launched and used in Albania, is provided in the Albanian language and in the correct form, taking into consideration the required knowledge from the potential users of the device. Other remaining accompanying information can be introduced in another language of another member state of the European economical zone, understood by any potential user.

**Article 7**

**Requirements for the Medical Device**

1. A medical device is designed, manufactured, packaged and labelled so that:

   a. when a medical device reaches the intended form by the manufacturer, its use is guaranteed for the purpose of which it is manufactured;
   b. if properly installed and used under the prescribed conditions, the device does not cause the deterioration of the quality of treatment, does not present a risk on life, health or the property of the patient, ordinary user or of a third person;
   c. the benefit regarding the health of the patient needs to be greater than the possible risks regarding the use of the device;

2. By the Decision of the Council of Ministers, the requirements on designing, manufacturing and packaging of medical devices and the information that accompanies the medical devices, are determined.

**Article 8**

**Introduction of Medical Devices that Fail the Conformity Test**

A medical device that fails to pass the conformity test can be presented in fairs or other commercial events, on the condition that the medical device should be accompanied by clearly visible information stating that the device should not be launched or operated until it complies with the requirements specified in this Law and in the legislation created in accordance with it.
CHAPTER III
CLASSIFICATION AND REGISTRATION OF MEDICAL DEVICES

Article 9
Classification of Medical Devices

1. In order to enable the implementation of the necessary procedures of the conformity assessment, a manufacturer is asked to classify the medical devices. Their differentiation is done in categories based on the possible risk that the device presents to the life and health of people and to the primary purpose of the manufacturer.

2. The medical devices, besides in vitro diagnostic medical devices and actively implantable medical devices, are organised into four categories: I, IIa, IIb and III.

3. In vitro diagnostic medical devices are classified as:
   a. medical devices that present a low risk to the patient;
   b. medical devices that present risk to the patient.

4. Medical devices specified in clause 3.b of this article are divided into list A and list B devices.

5. Actively implantable medical devices are not classified and they are assessed as medical devices that present risk.

6. The Council of Ministers determines regulations regarding the classification of medical devices.

7. If the manufacturer and the notified body do not agree on the proper implementation of the classification regulations, the case is directed to the State Agency of Medical Devices who decides on the classification of the device.

Article 10
State Agency of Medical Devices

1. The State Agency of Medical Devices is the accredited authority in the field of clinical engineering, supporting Albanian health care with the proper infrastructure of the technology for the medical devices.

2. The structure and its way of functioning is regulated by the Decision of the Council of Ministers.
Article 11
The Notifying Body

1. The notifying body is the organisation assigned by the Ministry of Health for performing the conformity assessment procedures of the medical devices.
2. The Ministry of Health notifies the European Commission and member states of the European economical zone regarding the notifying body that has been assigned.
3. The criteria for recognising the notifying body by the Ministry of Health are determined by Decision of the Council of Ministers.

Article 12
A person who acts as a notified body, allows the State Agency of Medical Devices to look at the documents that have information on:

a. qualifications of the contractors and the activities performed by the contractors in accordance with this law;
b. economical activities of notified bodies.

Article 13
Clinical Assessment of Medical Devices

1. The manufacturer provides a clinical assessment of the medical device before performing the conformity assessment to verify the conformity of a medical device with the specified requirements stated in article 7 of this law for the intended purpose and to determine any undesirable side effects that are caused by the medical device.
2. The clinical assessment of the actively implemented medical device and group III of medical devices is provided by the clinical information. The clinical information is based on the drafting of scientific and technical information regarding the use according to the intended purpose of the medical device and depending on the case, a written report that contains the critical assessment of this draft.
3. The persons involved in providing the clinical assessment guarantee the confidentiality of the information.

Article 14
Clinical Investigation of Medical Devices

1. The clinical investigation of the medical device is performed for the following purposes:
   
a. to verify that the performance of the device in normal usage conditions complies to the requirements specified in article 7 of this law.
b. to determine any undesirable side effect in normal usage conditions and to assess whether the medical device constitutes risk when presented to its intended purpose.

2. It is the responsibility of the manufacturer or the authorised representative to perform the clinical investigation. Besides the manufacturer or its authorised representative, the clinical investigation is also the responsibility of the professional user.

3. The manufacturer or his authorised representative guarantee the State Agency of Medical Devices the right to use this written report of clinical investigation, signed by the professional user who performs the investigation, which should contain the critical assessment of all data collected during the clinical investigation.

4. The information regarding the clinical investigation is confidential.

5. The Minister of Health defines the regulation for the procedure of performing the clinical investigation of the medical devices.

Article 15
Exercising the Right to Perform Clinical Investigation of the Medical Device

1. In order to perform a clinical investigation of a clinical device, the manufacturer or his authorised representative gets the approval of the Ministry of Health regarding clinical tests in accordance with the procedures and terms defined in the Regulation issued by the Minister of Health.
2. The manufacturer or his authorised representative present a written request for performing a clinical investigation at the State Agency of Medical Devices. The request contains information on:
   a. identification of the medical device that will be investigated;
   b. time of investigation;
   c. the approval of the Ministry of Health regarding clinical tests;
   d. the name of the professional user performing the investigation and the name of the person responsible for the investigation;
   e. the place, the date of commencement and the specified duration of the investigation;
   f. the declaration that, besides the aspects on which the medical device is being investigated, meets the requirements specified in article 7 of this law;
   g. the declaration that all protective measures regarding the health and safety of the patient have been taken for the purpose of the medical device under investigation.
3. The State Agency of Medical Devices provides permission for the organisation of the clinical investigation of the medical device or denies such permission based on the principles of protecting the health of the person and maintaining public order within:
a. 90 days after the date of receiving all necessary documentation in the case of the actively implanted medical device, the medical device of group III or group IIa or IIb that are manufactured for long-term use;
b. 30 days after the date of receiving all necessary documentation in the case of all other medical devices.

4. This article is not applicable for the medical devices that have the CE mark of conformity, except in the case of the investigation being performed regardless of the intended purpose of the device.
5. The presented information regarding the clinical investigation is confidential.

Article 16
Conformity Assessment of Medical Devices

1. A person who wishes to launch a medical device in his name, verifies that the manufactured device complies to its specific requirements by the conformity assessment. Following this verification, the person prepares a conformity declaration and places the CE mark of conformity on the medical device. The CE mark is not placed on medical devices subject to clinical investigation, medical devices made by order and medical devices for performance assessment.
2. After performing the conformity assessment, the notifying body issues a conformity certificate or an appendix for the certificate verifying the conformity of the medical device or the quality system.
3. The notifying body has the right to suspend or void the conformity certificate if the person specified in clause 1 of this article does not meet or ceases to meet the requirements of this Law or the legislation created in accordance with it, or if the conformity certificate should not have been issued. The conformity certificate is not suspended or made void if the manufacturer has implemented measures that eliminate the lack of conformity.
4. The procedure for the conformity assessment of the medical device is determined by Decision of the Council of Ministers.

Article 17

In the case of non-conformity of the medical device to the requirements of this Law and to the legislation developed in its application, the State Agency of Medical Devices will commence a supervising procedure with the scope of withdrawing this device from the market, inhibition or restriction of launching it and its availability. The State Agency of Medical Devices immediately informs the European Commission and the accredited authorities of the European Economical Zone for the commencement of a supervising procedure and for its performance and result.
Article 18
Systems for Medical Devices and Packages

1. Any person who collects/assembles the device with the CE mark in accordance with their intended purpose and in accordance with the usage limits specified by their manufacturers, will draft a declaration with the purpose of launching them as a system or package, stating that:

   a. he has verified the reciprocal compliance of the devices in accordance with the instructions of the manufacturers;
   b. he has acted in accordance with these instructions;
   c. he has packed the system or the package and has provided relevant information on the users including the relevant instructions from the manufacturers;
   d. all the activity of collecting the devices has undergone suitable methods for inside control and inspection.

2. If the terms specified in clause 1 of this article are not fulfilled, as in cases when the system or the package includes devices that do not have the CE mark or when the chosen combination of the devices does not conform to their initial intended use, the system or the package will be treated as a device in its own right and as such will be subject to the conformity assessment procedure of the medical devices in accordance to this law.

3. Any person who has sterilised the aforementioned systems stated in the first paragraph of this article, or other medical devices that have the CE mark, designed by the manufacturers to be sterilised before use, with its solution, will follow the conformity assessment procedure suitable for the scope of obtaining sterility. The person who sterilises a device, drafts a declaration stating that the sterilisation is conducted in accordance with the instructions of the manufacturer.

4. The information that accompanies the products specified in the first and the third paragraph of this article includes information on any assembled device.

5. The persons specified in clauses 1 and 3 of this article will retain the declarations in order that they can be made available to the State Agency of Medical Devices, if required, for a 5-year period following the date of their provision.

Article 19
Reporting and Investigating Un desirable Events
1. The Ministry of Health undertakes all the necessary steps to ensure that information can be obtained relating to any malfunction or damage/destruction of the characteristics and/or functioning of the medical device, technical factors related to them, as well as the unsuitability in labelling or instructions that:
   a. have led, may lead, might lead or might have led to the death of a patient, of a third person, of an ordinary user, to the deterioration of a patient’s health condition;
   b. deal with the damage of the characteristics and/or functioning of a type of medical device that has been continuously acknowledged by the manufacturer.

2. Every health care institution immediately notifies the State Agency of Medical Devices and the manufacturer regarding the circumstances specified in clause 1 of this article.

3. The manufacturer or his authorised representative informs the State Agency of Medical Devices for any undesirable event that happens during clinical investigation of a medical device.

4. A distributor of medical devices immediately informs the manufacturer of the medical device or his authorised representative for any undesirable event that could have been caused by a malfunction or damage of the characteristics and/or functioning of this device.

5. The State Agency of Medical Devices investigates the circumstances in which the undesired event happened and if possible, seeks the assistance of the manufacturer for this purpose.

6. After performing the assessment of the event, the State Agency of Medical Devices informs the following bodies on the process, investigation results and the relevant measures taken or considered: the institution where the event happened, the other institutions where it is assessed, the manufacturer or his authorised representative, the notifying body when it is involved in the conformity assessment of the medical device in relation to the undesirable event.

7. The persons that give information regarding the undesirable event, guarantee the protection of the personal information of the patient or ordinary user and the confidential information of the business that is made available in the process of investigating the undesirable event.

8. The State Agency of Medical Devices immediately informs the European Commission and the accredited authorities of the European Economic Zone member states about the undesirable event related to a supervising procedure that has commenced with the purpose of withdrawing such a device from the market, or to stop or restrict its launch and its availability.

The State Agency of Medical Devices in this notification defines whether the event is caused by failure to meet the requirements, the incorrect application of harmonised standards or unsuitability of the harmonised standards.

8. The Minister of Health defines the procedure and the format of the report for undesirable events.

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**Article 20**

**Retention of Documents for Medical Devices**
1. The manufacturer of a medical device, within five years from the production date of the last device of that particular type, allows the State Agency of the Devices to use the following documents that accompany the medical device:

a. declaration of conformity of the medical device;
b. the request that is presented to the notified body for the conformity assessment of the quality system;
c. the documents that describe the model, the production and the functioning of the medical device that enables the conformity assessment of the device;
d. the documents issued by the notifying body and the prepared reports during the inspection of the manufacturer;
e. the standard certificate of the examination.

Article 21
Database of Medical Devices, Persons Launching the Medical Devices and the Undesirable Events

1. The database of medical devices, persons launching the medical devices and of the undesirable events is a database of State Agency of Medical Devices. This database summarises:

1) the data that identifies the medical devices defined in Article 1. The notification of launching the medical device, the provision of the information on medical devices that are on the market and the persons that launch them, including a special notification if the blood products are used in a device;
2) the undesirable events and the circumstances in which they occurred as specified in Article 19, “Reporting and investigating undesirable events” of this Law;
3) the information on certificates of conformity issued by the notified bodies.

2. The State Agency of the Medical Devices is the authorised processor and the main processor of the database of medical devices, the person that launches the medical devices on the market and the undesirable events.
3. The database defined in clause 1 of this article is provided to the European database of medical devices and to any accredited authority of the European Economical Zone member states.

CHAPTER IV
PROFESSIONAL USE OF MEDICAL DEVICES

Article 22
Requirements for Health Care Provider Institution on the Professional Use of Medical Devices

1. A medical device is used in a professional manner solely for its intended purpose in accordance with the manufacturer’s instructions, taking into consideration the principles of medicine based on facts when, after investigating case by case the possible efficiency, the benefit and the alternative less harmful risks that serve the same purpose, it is noticed that the benefit for the patient’s health is much higher than the possible risks in the use of the device.

2. The owner of a medical device guarantees:
   1) the existence of the conditions required for the use of medical devices, according to the definitions described by the manufacturer;
   2) the existence of instructions for the use of the device in the place where it is used;
   3) the performance of installation and maintenance and when necessary, the reparation services from a competent person.

Article 23
Premises for Medical Devices

1. Before initiating the use of a medical device, the health care provision institution checks the technical conditions of the medical device and takes measures for the training of professional users, on the condition that these requirements are applicable for the medical device that is being operated.

2. In cases when the verification for the correct and safe functioning of a medical device is needed in order to be operated, the health care provision institution must prepare a report on the operation of the medical device.
STATE SUPERVISION

Article 24
The Competence of the State Supervision Authorities

The state supervision for the compliance of the requirements defined by this Law and the legislation developed in its application, is exercised by the Ministry of Health and by the State Agency of Medical Devices.

Article 25
The Rights and Obligations of Operators Exercising State Supervision

1. The clerk who exercises the state supervision has the right to:
   a. inspect the adherence of the requirements of this law and of the legislation developed in its application without obstruction and without prior notice;
   b. enter, for the purpose of supervision, inside the premises of a person who is subject to inspection, in the presence of the person subject to inspection, the representative or his employee.
   c. obtain the necessary information for the supervision, to inspect the relevant documents for the supervision along with its copies and to obtain copies of them;
   d. decide on the interventions that need to take place.

2. The clerks that exercise state supervision guarantee the confidentiality of the business and of the technical information they obtain, except in the cases when the declaration of this information is provided by law;

3. A person subject to the supervision should help the person that exercises it in the execution of the duties provided by law and the legislation developed in its application.

4. The manufacturers of medical devices that are subject to clinical investigation or those medical devices made to order, provide the possibility to the State Agency of Medical Devices to inspect the documents that enable the conformity assessment of the medical devices in accordance with the requirements of this law and legislation developed in its application:
   a) documents regarding the production, functioning and the expected effect of a device made to order;
   b) the general description of the medical device subject to clinical investigation, relevant projects and production methods, necessary explanations regarding the projects and the functioning of the devices, the results of the risk analysis, the results of the performed test and a list of harmonised standards observed. If the harmonised standards are not observed as a whole, there should be a description provided of the measures guaranteeing the conformity to the requirements of this law and of the legislation developed in its application.
   c) documents regarding the production, functioning and the expected effect of a medical device for the assessment of its functioning;
5. In the case of non-conformity of the medical device to the requirements of this Law and to the legislation developed in its application, the State Agency of Medical Devices commences a supervising procedure for the purpose of withdrawing this device from the market, inhibition or restriction of launching it and making it available. The State Agency of Medical Devices immediately informs the European Commission and the accredited authorities of the European Economical Zone for the commencement of a supervising procedure and for its performance and result.

6. When relevant, the State Agency of Medical Devices reserves the right to, within two years from launching a medical device with the CE mark, defined in article “The notification of launching the medical devices and the provision of information on the medical devices that are in the market” of this Law, to request a report from the manufacturer providing the information on the devices taken from the market.

7. The State Agency of Medical Devices reserves the right to oblige any person launching a medical device, to inform the public on the risks relating to this device or to provide that information through the person responsible.

8. The method of report utilised by the persons that perform the supervision is approved by the Minister of Health.

Article 26
The Inspection of the Conformity of Medical Devices to the Requirements

1. In the framework of state supervision, the State Agency of Medical Devices reserves the right, with the scope of inspecting the conformity of the medical device or its parts that enter the market, with a reasonable fee, to take the necessary amount of medical devices or their parts from the manufacturer of the medical device or the person that launches them and in certain cases, order the assessment services for the inspection of conformity of the medical devices or their parts.

2. In cases of suspicion, which can be evidenced, the State Agency of Medical Devices reserves the right to prohibit the launch of a medical device for the period of time necessary to perform a final control of the conformity of the medical device to meet the stated requirements.

3. Based on the inspection result of a medical device, the State Agency of medical Devices reserves the right to request:
   a) the provision of additional information regarding the utilisation of the device and the risks relating to the launch;
   b) that the manufacturer, his authorised representative or the person launching the device, to inform the users within a set period of time regarding the risks relating to the use of the medical device launched and the possibility of eliminating this risk;
   c) the withdrawal of a medical device from the market evidenced to be harmful, the banning of the product’s advertisement and depending on the situation, the elimination of the medical device.

4. If the expert notices that the medical device is conforming, the State Agency of Medical Devices meets all expenses of the service assessment service assigned for the inspection of the medical device, returns the medical device or compensates for the direct financial damage. If the expert notices that the device is not conforming, the expenses of
the assessment service are met by the manufacturer, the authorised representative or the person launching the device, taking into consideration the guidance issued by the State Agency of Medical Devices that should include, as an appendix, a copy of the document as proof for the expenses of the person that has conducted the assessment service.  
5. The method of report utilised by the persons performing the inspection is approved by the Minister of Health.

Article 27
Sanctions

1. Infringement of articles 6, 7 and of this law, when they do not constitute an offence, constitute as administrative crime and is punishable by a fine of up to 500,000 L.
2. The responsible authority for the enforcement and execution of the penalty is the State Agency of Medical Devices.
3. The procedures for the enforcement of the penalty and for the appeal are regulated in accordance with Law No. 7694, dated 7 April 1993 “On Administrative Crime”.

CHAPTER VI
FINAL PROVISIONS

Article 28
Issue of Regulations

1. The Council of Ministers has a responsibility to issue regulations in application to article 7 clause 2, article 9 clause 6, article 10 clause 2, article 11 clause 3 and article 16 clause 2 within six months from the enforcement date of this law.
2. The Ministry of Health has a responsibility to issue regulations in application to article 5 clause b, 14 clause 5, article 19 clause 8, article 25 clause 8 and article 26 clause 5 within six months from the enforcement date of this law.

Article 29
The Utilisation of Medical Devices Launched Prior to the Enforcement Date of this Law

The medical devices that are launched in compliance with the procedure in force at the time of the enforcement of this law and that are considered to be safe, may still be used until the end of their expected service life.

Article 30

Date of Enforcement

This law will be enforced fifteen days following its publication in the “Official Journal”.