THE CROATIAN PARLIAMENT

Pursuant to Article 89 of the Constitution of the Republic of Croatia, I hereby issue the

DECISION

PROMULGATING THE MEDICAL DEVICES ACT

I hereby promulgate the Medical Devices Act passed by the Croatian Parliament at its session on 14 June 2013.

Class: 011-01/13-01/135

Reg. No.: 71-05-03/1-13-2

Zagreb, 18 June 2013

The President

of the Republic of Croatia

Ivo Josipović, m. p.

MEDICAL DEVICES ACT

I General provisions

Article 1

(1) In order to ensure quality, safety and performance requirements of medical devices that are considered devices of particular importance for health protection of humans this Act shall stipulate the requirements for medical devices, clinical trials of medical devices, entry into the register of medical devices manufacturers, conformity assessment and CE markings, conformity assessment bodies, registration, placing on the market, advertising, vigilance and supervision and control of medical devices.

(2) The provisions of this Act shall apply to medical devices and their accessory, including *in vitro* diagnostic medical devices and active implantable medical devices.

(3) The terms used in this Act and in the relevant bylaws adopted on the basis of this Act shall equally refer to common gender - masculine and feminine gender, regardless of the fact whether they have been used in the masculine or feminine form.

Article 2

(1) This Act shall transpose the following directives into the legislative framework of the Republic of Croatia:

1. Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20/07/1990),

2. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12/07/1993),

3. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, (OJ L 331, 7.12.1998),

4. Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivates of human blood or human plasma (OJ L 313, 13.12.2000),

5. Commission Directive 2003/32/EC of 23 April 2003 introducing detailed specifications as regards the requirements laid down in Council Directive 93/42/EEC with respect to medical devices manufactured utilising tissues of animal origin (Text with EEA relevance), (OJ L 105, 26. 4. 2003.),

6. Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market (Text with EEA relevance), (OJ L 247, 21.9.2007).

(2) This Act shall stipulate the application of the following regulations:

1. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (Text with EEA relevance), OJ L 218, 13.8.2008,

2. Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices (Text with EEA relevance), (OJ L 72, 10. 3. 2012),

3. Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin (Text with EEA relevance) (OJ L 212/3, 9. 8. 2012).

Article 3

For the purposes of this Act the following definitions shall apply:

1. ‘Medical device’ means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap,

— investigation, replacement or modification of the anatomy or of a physiological process,

— 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;

2. 'Accessory' means an article which whilst not being a medical device is intended specifically by its manufacturer to be used together with a medical device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device;

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

— concerning a physiological or pathological state,

— concerning a congenital abnormality,

— to determine the safety and compatibility with potential recipients,

— to monitor therapeutic measures.

Specimen receptacles are considered to be *in vitro* diagnostic medical devices. 'Specimen receptacles' are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination.

Products for general laboratory use are not *in vitro* diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination;

'Accessory' means an article which, whilst not being an *in vitro* diagnostic medical device, is intended specifically by its manufacturer to be used together with any *in vitro* diagnostic medical device to enable that device to be used in accordance with its intended purpose.

Invasive sampling devices or those which are directly applied to the human body for the purpose of obtaining a specimen shall not be considered to be accessories to *in vitro* diagnostic medical devices;

4. 'Medical device for self-testing' means any *in vitro* diagnostic medical device intended by the manufacturer to be able to be used by lay persons in a home environment;

5. ‘Medical device for performance evaluation’ means any *in vitro* diagnostic medical device intended to be subject to one or more performance evaluation studies in laboratories or in other appropriate environments;

6. ‘Calibrators and control materials’ refer to any substance, material or article intended by their manufacturer either to establish measurement relationships or to verify the performance characteristics of any *in vitro* diagnostic medical device in conjunction with the intended use of that device. Certified reference materials and materials used in quality system assessments in the manufacturing process and in laboratories shall not be considered *in vitro* diagnostic medical devices.

7. *In vitro* diagnostic medical device is a new device provided that:

a) it has not been placed on the market within the territory of the Republic of Croatia and/or the European Union in the time period of previous three years running relating accordingly to a particular analyte or some other parameter,

b) the procedure involves an analytical technology that has not been used relating accordingly to a particular analyte or some other parameter in the Republic of Croatia and/or the European Union over the previous three years running.

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

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

10. ‘Custom-made device’ means any device specifically made in accordance with a duly qualified medical practitioner's or dental practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient.

The abovementioned written prescription may also be made out by any other person authorized by virtue of his professional qualifications to do so in line with separate laws.

Mass-produced medical devices which need to be adapted to meet the specific requirements of the medical practitioner or dental practitioner shall not be considered to be custom-made medical devices;

11. ‘Device intended for clinical investigation (clinical trial)’ means any device intended for use by a duly qualified medical practitioner when conducting investigations in an adequate human clinical environment. For the purpose of conducting clinical investigation, any other person who, by virtue of his professional qualifications, is authorized to carry out such investigation shall be accepted as equivalent to a duly qualified medical practitioner;

12. ‘Clinical data’ means the safety and/or performance information that is generated from the use of a medical device. Clinical data are sourced from:

— clinical investigation(s) of the medical device concerned;

— clinical investigation(s) of the medical device concerned or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated;

— published and/or unpublished reports on other clinical experience of either the medical device in question or a similar medical device for which equivalence to the device in question can be demonstrated;

13. 'Clinical investigation plan (protocol)' is a document that describes the objectives, design, methodology, statistical considerations and organisation of a medical device clinical investigation. The term 'clinical investigation plan' also includes all versions of the general clinical investigation plan, its revisions and supplements.

14. 'Sponsor of the clinical investigation' means any legal or natural person who is responsible for the commencement of the clinical investigation, its implementation and/or who finances the clinical investigation.

15. 'Clinical trial applicant' means the sponsor of the clinical investigation who has its registered place of business in the European Union or any legal or natural person with its registered place of business in the European Union who has been authorised by the sponsor to lodge a clinical trial application for and on his behalf.

16. *'Central Ethics Committee'* shall mean an independent body consisting of both medical and non-medical professionals whose responsibility is to ensure the protection of the rights, safety and well-being of clinical trial subjects and to guarantee the aforementioned protection by, among other things, giving opinions on clinical investigation plans (trial protocols), suitability of investigators, legal persons on whose premises clinical investigations are conducted, equipment, methods and documents to be used for informing the trial subjects and obtaining their informed consents. The Central Ethics Committee shall be appointed by the minister in charge of health (hereinafter: "minister").

17. 'Good clinical practice' means a set of internationally recognized ethical and scientific requirements which should be met for the design, conduct, recording and reporting on clinical trials.

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

19. 'Natural person' means a person who autonomously performs an economic activity on a permanent basis in conformity with a separate law, or a person with its registered place of business in the European Union who in conformity with the relevant rules of the EU Member State autonomously performs a business activity.

20. ‘Manufacturer of a medical device’ means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a medical device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

21. ‘Intended purpose (intended use)’ means the use for which the medical device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional material;

22. ‘Placing on the market’ means the first making available in return for payment or free of charge of a medical device other than a medical device intended for clinical investigation, with a view to distribution and/or use on the EU market, regardless of whether it is new or fully refurbished;

23. ‘Putting into service’ means the stage at which a medical device has been made available to the final user as being ready for use for the first time for its intended purpose. In the case of active implantable medical devices putting into service means making available to the medical profession for implantation;

24. ‘Device subcategory’ means a set of devices having common areas of intended use or common technology;

25. ‘Generic device group’ means a set of medical devices having the same or similar intended uses or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;

26. ‘Single use device’ means a medical device intended to be used once only for a single patient.

27. ‘Medical devices manufactured utilising animal tissue which is rendered non-viable or non-viable products derived from animal tissue’ means devices that must meet essential requirements relating to the risk of transmitting transmissible animal spongiform encephalopathies (TSE), under the normal conditions of use, to patients or other persons, and which have been identified as such during the conformity assessment procedure.

28. ‘Vigilance of medical devices’ comprises tools designed to facilitate the collection and evaluation and understanding of information as well as responding to new or emerging information pertaining to the risks associated with the use or application of medical devices, particularly relating to reporting of adverse incidents, interactions with other substances or products, side effects, counterfeiting, impaired efficacy, performance failures and poor construction or design of medical devices.

29. ‘Adverse event or incident relating to a medical device’ means any malfunction of the medical device, performance failures, absence or impaired efficacy of the medical device, inadequacy of the effects of the medical device, including any deficiencies in labelling, instructions or packaging, where these adverse events lead or might have led to a death or a serious deterioration in health of the patient, user or third party.

30. ‘Authorised representative of the manufacturer of the medical device’ means any legal or natural person established in the European Union who, explicitly designated in writing by the

manufacturer with its seat in a third country, acts and may be addressed by authorities and bodies in the European union instead of the manufacturer with regard to the latter's obligations within the territory of the European Union;

31. 'Third countries' means countries that are not Member States of the European Union or the European Economic Area.

32. 'Wholesale of medical devices' means purchase of medical devices and their resale to natural or legal persons with the view to performing their professional and registered activity, including the purchase, receipt, storage, resale and delivery, with an exception of the delivery to the end user - sole customer.

33. 'Retail of medical devices' means ordering, storage, dispensing and resale of the medical device to the end user – intended for use by a sole customer.

34. 'Import of a medical device' means wholesale of a medical device which has been imported from third counties to the territory of the European Union.

35. 'Good practice in the wholesale of medical devices' involves storage and transport standards relating to the wholesale of medical devices particularly ensuring the storage organisation, carrying out and control in line with the statutory requirements, as well as the transport of medical devices to its wholesale users.

36. 'Conformity assessment of a medical device' means any activity relating to direct or indirect activities used to demonstrate the compliance with the essential requirements set out in the technical documentation relating to a particular device.

37. 'Conformity assessment body' means an independent laboratory, enforcement authority, regulator or supervision authority designated by the minister to carry out the conformity assessment procedure relating to medical devices.

38. 'Notified body for conformity assessment' (hereinafter: notified body) means a body that has been notified by the relevant central public administration authority to the European Commission to carry out conformity assessment procedures and that has been assigned the identification number by the European Commission.

39. 'Croatian standard' means a publically available standard which has been adopted by the Croatian national standards organization.

40. 'Certification of conformity' means a document issued by a notified body on the basis of which it guarantees that the essential requirements, which are in line with the requirements set out in this Act and the relevant bylaws adopted pursuant to this Act or the relevant EU rules, have been met concerning a particular manufacturing process or a medical device.

41. 'Declaration of conformity' means a document issued by the manufacturer of a medical device on the basis of which it guarantees that a manufacturing process or a medical device meets the essential requirements which are in line with the requirements set out in this Act and the relevant bylaws adopted pursuant to this Act or the relevant EU rules.

Article 4

(1) The provisions of this Act shall apply to any medical device intended for administration of a medicinal product.

(2) Where a medical device incorporates a medicinal product as an integral part and where this integral product is intended exclusively for use in the given combination and which is not reusable, the Act on Medicinal Products shall apply. As far as the safety and performance-related device features of the medical device are concerned, they must comply with the essential requirements under this Act.

(3) Where a medical device incorporates as an integral part an ancillary medicinal substance which may be used separately and acts upon the body with action that is ancillary to that of the device, this medical device shall be assessed under the provisions of this Act, whereas the medicinal substance shall be assessed under the Act on Medicinal Products and the relevant bylaws adopted on the basis of the latter.

(4) The provisions of this Act shall apply also to *in vitro* diagnostic medical devices manufactured from tissues, cells or substances of human origin.

Article 5

The provisions of this Act shall not apply to:

- medicinal products;

- cosmetic products;

- human blood, blood products, plasma or blood cells of human origin or to devices which incorporate at the time of placing on the market such blood products, plasma or cells;

- transplants or tissues or cells of human origin nor to products incorporating or derived from tissues or cells of human origin,

- transplants or tissues or cells of animal origin, unless a device is manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissue;

- products which are a combination of a medicinal product and a medical device, containing viable cells or tissues or non-viable cells or tissues, where the cells or tissues have been considered to be the principal mode of action of the combination product;

- *in vitro* diagnostic medical devices which are manufactured and used only within the same health institution and on the premises of their manufacture or used on premises in the immediate vicinity without having been transferred to another legal entity;

- personal protective equipment and substances in conformity with separate rules.

Article 6

(1) Medical devices referred to in Article 3, point 27 of this Act are medical devices originating from bovine, ovine and caprine species, deer, elk, mink and cats.

(2) The provisions of this Article shall not apply to medical devices which are not intended to come into contact with the human body or which are intended to come into contact with intact skin only.

(3) Special requirements for medical devices referred to under paragraph 1 of this Article shall be regulated by the minister in an ordinance.

Article 7

The removal, collection and use of tissues, cells and substances of human origin shall be governed, in relation to ethics, by the principles laid down in the Convention of the Council of Europe for the protection of human rights and dignity of the human being with regard to the application of biology and medicine and by any separate rules on this matter.

Article 8

(1) The Croatian Agency for Medicinal Products and Medical Devices of Croatia (hereinafter: "Agency") shall cooperate with the competent authorities of the EU Member States, the European Commission and other competent authorities and exchange information with the view to uniformity in the application of the rules covering medical devices.

(2) The Agency shall enter into the European Database on Medical Devices (hereinafter: EUDAMED) the following data:

– data on manufactures and authorised representatives of manufacturers of medical devices with their registered place of business in the Republic of Croatia and on medical devices which they place on the market, with an exception of the medical devices which have been manufactured for the sole use of a particular patient,

– data on issued, withdrawn, modified, complemented and suspended certifications on conformity of medical devices,

– data on vigilance of medical devices.

(3) The data on clinical investigations of medical devices shall be entered to EUDAMED data base by the ministry in charge of health (hereinafter: ministry).

II Requirements for medical devices

Article 9

(1) Medical devices may be made available on the market of the Republic of Croatia (hereinafter: placing on the market) only if they do not compromise the safety and health of patients, users and other persons and only if they have been properly manufactured, correctly installed, maintained and used in accordance with their intended purpose.

(2) Medical devices must meet the essential requirements taking into account the intended use of a particular medical device.

(3) Medical devices emitting ionized radiation must also meet the conditions laid down by the rules regulating the ionizing radiation protection rules.

(4) Where medical devices are also machines pursuant to a special rule, it must accordingly comply with the essential rules for machines.

(5) Where the intended use of a medical device is such that at the same time it is used as personal protective equipment, the medical device in question must also accordingly comply with the essential requirements for personal protective equipment.

(6) The essential requirements for medical devices shall be regulated by the minister in an ordinance.

Article 10

(1) Where a medical device is in conformity with the Croatian standards which comply with the harmonized European standards, it shall be presumed that it meets the relevant essential requirements.

(2) The minister publishes the list of the Croatian standards for medical devices in the *Official Gazette*.

(3) The reference to standards shall include the monographs of the Croatian Pharmacopoeia and the monographs of the European *Pharmacopoeia* notably on surgical sutures and on interaction between medicinal products and materials used in devices containing such medicinal products.

(4) For *in vitro* diagnostic medical devices in List A in Annex II whose intended use is for *in vitro* diagnostics and which is a constituent part of the ordinance referred to in Article 13 paragraph 2 of this Act, and where necessary for *in vitro* diagnostic medical devices in List B in Annex II whose intended use is for *in vitro* diagnostics which is a constituent part of the ordinance referred to in Article 13 paragraph 2 of this Act, the reference to norms shall mean at the same time the reference to common technical specifications for *in vitro*-diagnostic medical devices.

(5) The common technical specifications shall establish appropriate performance evaluation and re-evaluation criteria for *in vitro* diagnostic medical devices, batch release criteria for *in vitro* diagnostic medical devices, reference methods and reference materials.

(6) The common technical specifications shall be published in the *Official Journal of the European Union*.

(7) Manufacturers of medical devices shall be required to comply with the common technical specifications regarding the *in vitro* diagnostic medical device.

(8) If for duly justified reasons manufacturers do not comply with the aforementioned common technical specifications regarding *in vitro* diagnostic medical devices they must adopt solutions of a level at least equivalent thereto.

Article 11

(1) Where it has been ascertained that a medical device that meets the requirements provided in Article 9 of this Act, when correctly installed, maintained and used for its intended purpose may compromise the health and/or safety of patients, users or other persons, the Agency shall acting upon its own initiative (*ex officio*) or upon the initiative of a pharmaceutical inspector take the following interim measures:

- withdraw such medical devices from the market,

- restrict their being placed on the market or put into service.

(2) The Agency shall immediately inform the European Commission of any such measures taken under paragraph 1 of this Article, indicating the reasons for its decision and, in particular whether noncompliance is due to:

- failure of the medical device to meet the essential requirements,

- incorrect application of the standards referred to in Article 10 of this Act,

- shortcomings in the standards themselves.

(3) Where it has been established that a medical device does not meet the essential requirements, and where a non-complying device bears the CE marking, the pharmaceutical inspector shall take appropriate action and shall inform the Agency thereof.

(4) The Agency shall inform the European Commission on the measures taken under paragraph 3 of this Article.

Article 12

(1) Each medical device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and must identify the manufacturer.

(2) This information referred to in paragraph 1 of this Article shall comprise the data on the label or in the instructions for use of the medical device.

(3) By way of derogation from paragraph 1 of this Article in duly justified and exceptional cases no such instructions for use are needed for medical devices of Class I and IIa if they can be used properly and safely without them.

(4) By way of derogation from paragraph 1 of this Article in duly justified and exceptional cases no such instructions for use are needed for *in vitro* diagnostic medical devices which if they can be used properly and safely without them.

(5) The instructions for use and labelling of the medical device must be in the Croatian language and appear in a visible and legible and form.

(6) Where the instructions for use and labelling referred to in paragraph 5 of this Article are translated the Croatian language, the translation of the instruction for use and marking of the

medical device must equally correspond to the original instructions for use and marking of the medical device.

(7) The instructions for use of medical devices exclusively intended for use by medical institutions must be supplied in a language which is known by the user.

(8) The instruction referred to in paragraph 7 of this Article for medical devices referred to in Article 3 paragraph 1 of the Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices, may be in electronic form in line with the provisions of the latter.

Article 13

(1) Medical devices are grouped into the following risk categories as follows:

- Class I - medical devices regarded as low risk for the users,
- Class IIa - medical devices regarded as medium risk for the users,
- Class IIb - medical devices regarded as high risk for the users,
- Class III - medical devices regarded as the highest risk for the users.

(2) Detailed requirements and classification rules for medical devices and *in vitro* diagnostic medical devices shall be regulated by the minister in an ordinance.

Article 14

(1) In the event of a dispute between the manufacturer and the notified body, resulting from the application of the classification rules, the matter shall be referred to the competent authority to which the notified body is subject.

(2) Where it is considered that the classification rules for medical devices require adaptation in the light of technical progress and any information which becomes available under the information system, the Agency may submit a duly substantiated request to the European Commission in view to taking the necessary measures for adaptation of classification rules for medical devices.

Article 15

The Agency shall submit a duly substantiated request to the European Commission and ask it to take the necessary measures in the following situations:

- if it considers that the application of the classification rules requires a decision with regard to the classification of a given medical device or category of devices;

- if it considers that a given medical device or family of medical devices should be classified in another class;

- if it considers that the conformity of a medical device or *in vitro* diagnostic medical device should be established by applying some other conformity assessment procedure;

- if it considers that a decision is required as to whether a particular product should be classified into a particular product group.

Article 16

(1) Any manufacturer who puts medical devices bearing the CE marking together within their intended purpose and within the limits of use specified by their manufacturer, in order to make them available i.e. place them on the market as a system or procedure pack, shall draw up a declaration by which he states that:

(a) he has verified the mutual compatibility of the medical devices in accordance with the manufacturers' instructions and has carried out his operations in accordance with these instructions;

(b) he has packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers;

(c) the whole activity is subjected to appropriate methods of internal control and inspection.

(2) The systems and the procedure packs referred to in paragraph 1 of this Article do not have to bear a CE marking.

(3) Where the conditions referred to above in paragraph 1 of this Article are not met, as in cases where the system or procedure pack incorporate devices which do not bear a CE marking or where the chosen combination of devices is not compatible in view of their original intended use, the system or procedure pack shall be treated as a medical device in its own right and as such be subjected to the relevant conformity assessment procedure.

Article 17

(1) Any manufacturer who sterilises, for the purpose of placing on the market, systems or procedure packs shall follow one of the procedures for the application of the quality system approved for sterilisation.

(2) The manufacturer shall secure sterility of the medical devices referred to in paragraph 1 of this Article until the sterile package is opened or damaged.

(3) Any legal and natural person shall before the use of a medical device that in accordance with the manufacturer's instruction must be sterilised before use, carry out the procedure of sterilisation following the manufacturer's instructions and applying the quality system approved for sterilisation.

(4) The manufacturer of the systems or procedure packs shall draw up a declaration stating that sterilisation has been carried out in accordance with the manufacturer's instructions concerning the particular medical devices which are integral parts of the system or procedure pack.

(5) Systems and procedure packs referred to in paragraph 1 of this Article do not have to bear an additional CE marking.

(6) Systems and procedure packs referred to in paragraph 1 of this Article shall be accompanied by the information which includes the instruction for use supplied by the manufacturers of the medical devices which have been put together in systems or procedure packs.

(7) The declarations referred to in paragraph 4 of this Article and Article 16 of this Act shall be kept by the manufacturer and made available to the competent authority upon request of the latter for a period of five years.

Article 18

The Agency shall provide professional advice upon a request submitted by legal or natural persons relating to the following:

– translations of instructions for use and marking of medical devices,

– classification of devices in categories of medical devices,

– classification of medical devices in appropriate classes according to the degree of risk.

III Clinical investigation of medical devices (clinical trials)

Article 19

(1) A clinical investigation (clinical trial) of a medical device shall mean any investigation undertaken to assess the safety and performance of a medical device in accordance with its intended purpose.

(2) Safety and performance of *in vitro* diagnostic medical devices shall be assessed on the basis of performance evaluation studies.

Article 20

(1) A clinical investigation of a medical device shall be conducted in a legal person fulfilling the criteria laid down by the minister in an ordinance.

2) A clinical investigation of a medical device may be conducted by a natural or legal person who has been authorised for the conduct of this particular investigation by the minister.

(3) A clinical investigation of a medical device shall be conducted in a legal person referred to in paragraph 1 of this Article at the cost of and upon the request of the person applying for the clinical investigation of the medical device (clinical trial applicant).

Article 21

(1) The authorisation for the clinical investigation of a medical device shall be issued by the minister on the basis of the complete documentation and the positive opinion of the Central Ethics Committee.

(2) The authorisation for the clinical investigation of a medical device shall be given or rejected within a time period of 60 days from the day of the receipt of the complete application.

(3) Where the minister does not give or reject the authorisation for the conduct of a clinical investigation within the time period referred to in paragraph 2 of this Article, the authorisation shall be deemed granted.

(4) The authorisation referred to in paragraph 1 of this Article shall be given or rejected by way of a decision against which no appeal is allowed but the injured party may initiate an administrative dispute.

(5) The costs of authorisation shall be borne by the person applying for the clinical investigation (clinical trial applicant).

(6) The criteria for the conduct of the clinical investigation of a medical device, necessary documentation and the opinion of the Central Ethics Committee shall be regulated by the minister in an ordinance.

Article 22

(1) After the commencement of the clinical investigation the sponsor of the clinical investigation shall be required to notify any revisions of the documentation or the clinical trial procedure.

(2) The revisions of the clinical investigation shall be authorised or rejected by the minister within a time period which may not exceed 30 days from the day of the receipt of the complete application by way of a decision against which no appeal is allowed but the injured party may initiate an administrative dispute.

Article 23

(1) A clinical investigation of a medical device may be conducted only subject to the informed consent of a clinical trial subject.

(2) A clinical investigation of a medical device in children may be conducted only if a clinical trial conducted in adults cannot provide satisfactory results.

(3) By way of exception, an informed consent of a person who is unconscious, suffering from a severe mental illness, incapacitated adults or minors, may be given by a legal representative or a guardian.

(4) Persons referred to in paragraphs 1 and 3 of this Article may revoke the informed consent to participate in a clinical trial at any time.

(5) A clinical investigation shall not be conducted if the possible risks of the administration of the medical device outweigh the medical justification of the investigation of the medical device.

(6) A clinical investigation may not be conducted on prisoners and persons who may be coerced into giving consent to participate in a clinical trial.

Article 24

(1) The principles of medical ethics as well as compulsory protection of subjects' privacy and data shall be observed during clinical trials of medical devices in line with an ordinance on clinical trials of medical devices and good clinical practice issued by the minister.

(2) A clinical investigation of medical devices may take place only on the premises of a legal persons referred to in Article 20 of this Act who entered into a clinical trial agreement with a person who has lodged a clinical trial application (clinical trial applicant).

(3) The agreement referred to in paragraph 2 of this Article shall specify the total cost of the clinical trial of the medical device and the cost to be incurred by the clinical trial applicant the sponsor of the clinical trial, including the costs of medical and other services incurred by the legal persons referred to in Article 20 of this Act as well as the compensations for the investigators and subjects.

(4) The investigators' and subjects' compensations referred to in paragraph 3 of this Article shall be paid by the clinical trial applicant or the sponsor to the legal person who entered into the clinical trial agreement dealing with the clinical investigation of the medical device.

Article 25

The provisions of Articles 19 to 24 of this Act shall also apply to clinical trials when they are conducted on a medical device holding a certificate of conformity if the purpose of the investigation concerned is the use of this medical device for some other intended purpose than the one obtained during the relevant conformity assessment procedure.

Article 26

(1) If it deems necessary the ministry shall take appropriate measures as to assure safety and health of humans. In case that a clinical trial has been rejected authorisation or where a clinical trial has been suspended, the ministry shall communicate to all EU Member States and the European Commission of its decision indicating the reasons.

(2) Where a clinical trial has been substantially amended or suspended, the ministry shall inform the interested EU Member States on the measures taken and indicate the reasons for its actions.

(3) The sponsor of the clinical trial shall notify the competent authorities of the interested EU Member States about the completion of the clinical trial, and where the clinical trial has been suspended before its completion, it shall provide the notification stating the reasons for suspension. In the event of the early termination of the clinical trial due to safety reasons, the notification concerned shall be forwarded to all EU Member States and to the European Commission.

IV Manufacturers responsibilities

Article 27

(1) A legal or natural person with its registered place of business in the Republic of Croatia who manufactures or makes a medical device, including the medical devices referred to in Articles 16 and 17 of this Act (hereinafter: manufacturer of a medical device) shall: :

– ensure that the medical device that he manufactures has been designed and manufactured in accordance with the requirements provided by this Act,

– carry out the classification of the medical device according to the associated risk, draw up the relevant technical documentation and conduct or ensure the conduct of an applicable conformity assessment procedure for the medical device concerned,

– draw up the conformity declaration and affix the CE marking to the medical device in question,

– keep available the technical documentation and the conformity declaration for at least five years after the medical device has been placed on the market,

– ensure the procedures with the view to pertaining the conformity of the batch or serial,

– properly label and mark the medical device and supplement it with the instructions for use referred to under Article 12 of this Act, ,

– undertake corrective actions where it can be assumed or where there is a reason to believe that the medical device which has been placed on the market does not comply with the provisions of this Act.

(2) The manufacturer of a medical device shall be insured against harmful effects which might occur by the use of the medical device.

(3) The responsibilities of the manufacturer of a medical device laid down by the provisions of this Act refer both to a legal and a natural person who assembles, packages, processes, fully refurbishes and/or labels medical products with a view to their being placed on the market under his own name.

(4) The responsibilities referred to under paragraphs 1 and 2 of this Article do not apply to the person who assembles or adapts devices already on the market to their intended purpose for an individual patient.

Article 28

(1) The manufacturer of a medical device shall within the period not exceeding 15 days from the start of performing its economic activity file an application for entry into the register of medical devices manufacturers kept by the Agency.

(2) The application for entry into the register of manufacturers of medical devices shall be submitted by:

– the manufacturers of medical devices with their place of establishment in the Republic of Croatia,

– the authorised representatives of manufacturers from third countries, who have their seat in the Republic of Croatia.

(3) The decision of the Agency on the entry of a manufacturer of a medical device into the register of manufacturers of medical devices shall be adopted within the time period of 60 days from the day of the receipt of the complete request.

(4) Against the decision referred to in paragraph 3 of this Article no appeal is allowed but the injured party may initiate an administrative dispute.

Article 29

(1) Following the registration of the medical device manufacturer in the register of manufacturers of medical devices, the register holder filing for entry into the register of manufacturers of medical devices shall notify to the Agency any amendments to the documentation on the basis of which the Agency has authorised the entry into the register.

(2) If the amendment to the documentation referred to in paragraph 1 of this Article requires also an amendment to the entry into the register, the Agency shall take a decision thereon. Against this decision no appeal is allowed but the injured party may initiate an administrative dispute.

(3) The decision referred to in paragraph 2 of this Article shall be rendered or rejected by the Agency, depending on the subject and scope of the amendment, within a time period not exceeding 30 days from the day of receipt of the complete application.

Article 30

(1) The Agency shall remove the manufacturer from the register of manufacturers of medical devices:

– upon a substantiated request of the registration holder,

– acting on its own initiative where it has been established that the manufacturer has been registered into the register in contravention of the provisions of this Act and the bylaws adopted pursuant to this Act,

– on the basis of other justified reasoning.

(2) The removal of the manufacturer of the medical device from the register of manufacturers of medical devices shall be based on the decision of the Agency against which no appeal is allowed but the injured party may institute an administrative dispute.

(3) The decision on removal of the manufacturer from the manufacturers register shall be issued by the Agency within a time period not exceeding 30 days.

(4) The fees relating to the entry into the register of manufacturers of medical devices, rejection of entry, amendments to the entry and removal from the register of manufacturers of medical devices on the request of the register holder shall be set by the Agency, subject to the prior consent of the minister, whereas the costs relating to the above mentioned procedures shall be borne by the applicant or the registration holder.

(5) The method of the registration into the manufacturers register, the amendments to the entry, the removal of a manufacturer from the manufacturers register and the documentation necessary for the registration shall be regulated by the minister in an ordinance.

V Conformity assessment and CE marking

Article 31

(1) The conformity assessment procedure relating to a medical device is a procedure on the basis of which it is established and assessed whether the medical device or the manufacturing of the medical device meets the requirements laid down by this Act and the bylaws adopted pursuant to this Act.

(2) The conformity assessment procedure relating to a medical device establishing its conformity with the essential requirements shall be conducted in accordance with the classification of the medical product concerned.

(3) Where the conformity assessment procedure involves the intervention of a notified body, the manufacturer may apply to a body of his choice within the framework of the tasks for which the body has been notified with the seat in any EU Member State.

Article 32

(1) Before placing on the market of a medical device the manufacturer shall draw up a declaration on conformity in respect with the medical device in question and affix the CE marking of conformity.

(2) The CE marking of conformity do not have to be affixed to medical devices intended for clinical investigations, custom-made devices and *in vitro* diagnostic medical device for performance evaluation.

(3) The medical devices at trade fairs, exhibitions, demonstrations shall also not bear the CE marking. These devices must be provided a visible sign clearly indicating that such devices cannot be marketed or put into service.

Article 33

(1) The CE marking of conformity must appear in a visible, legible and indelible form on the device or its sterile pack, where practicable and appropriate, and on the instructions for use.

(2) The CE marking shall be accompanied by the identification number of the notified body responsible for conformity assessment if the body concerned has been involved in the conformity assessment procedure.

(3) It is prohibited to affix CE marks of conformity to medical devices if the medical device concerned does not meet the criteria laid down by this Act.

(4) It is prohibited to affix CE marks within the meaning of this Act if the device concerned does not constitute a medical device.

(5) It is prohibited to affix marks or inscriptions which are likely to mislead third parties with regard to the meaning or the graphics of the CE marking.

Article 34

The Agency may, acting on its own initiative or based on the duly justified request of the applicant, with a prior consent of the minister, authorise making available on the market, in other works placing on the market and putting into service, also the medical devices that have not been subject to conformity assessment in exceptional cases such as epidemics, poisoning, nuclear or radiological accident or similar, but also under other circumstances where human health must be protected.

Article 35

The conformity assessment procedures, the content of the declaration on conformity and the CE marking shall be regulated by the minister in an ordinance in accordance with the previously obtained opinion of the minister in charge of the economy.

VI Conformity assessment bodies

Article 36

(1) Before it becomes operative, a conformity assessment body with its place of establishment in the Republic of Croatia carrying out the activities relating to conformity assessment of medical devices must have the authorisation issued by the minister.

(2) The criteria for the authorisation referred to in paragraph 1 of this Article shall be regulated by the minister in an ordinance.

Article 37

(1) The conformity assessment authority shall:

– have available sufficiently scientific staff who possess adequate experience and knowledge necessary to assess the medical functionality and performance of medical devices and their quality and quality systems in the manufacturing process,

– have adequate premises, instruments and equipment,

– a quality assurance system in place,

– keep the necessary documentation record on conformity assessment procedures and verification of medical devices as well as documentation on manufacturers of medical devices.

(2) A conformity assessment authority may in the supplement to its application for authorisation referred to in Article 36 paragraph 1 of this Act provide the certificate of accreditation issued by the Croatian national accreditation body.

(3) The certificate of accreditation referred to in paragraph 2 of this Article shall prove the competence of the conformity assessment authority and its compliance with the requirements set by the Croatian standards which thereby accept the relevant harmonized European standards.

Article 38

(1) The authorisation referred to in Article 36 paragraph 1 of this Act shall be granted to the conformity assessment body by the minister within 60 days from the day of the receipt of the complete application, whereas a prior opinion thereon shall be given by the expert committee.

(2) The expert committee referred to in paragraph 1 of this Article shall be appointed by the minister.

(3) Where the application is incomplete i.e. if it does not contain the relevant statutory data and documentation the minister shall by means of a procedural order request from the applicant to rectify the problem within a time period which shall not exceed 30 days from the day of the receipt of the procedural order.

(4) Where the minister requests from the applicant to supply additional data to the application concerned, the time limit referred to in paragraph 1 of this Article shall not run as long as the additional data has been received. Also the time limit shall not run during the period granted to the applicant with the view to submitting its written or oral argumentation.

(5) The authorisation shall be given to the compatibility assessment body by means of a decision against which no appeal is allowed but the injured party may initiate an administrative dispute.

(6) The costs of issuance of authorisation, rejection of authorisation or the withdrawal of authorisation referred to in paragraph 1 of this Article shall be borne by the applicant.

(7) The ministry shall within the time period of 15 days from the day of the adoption of the decision referred to in paragraph 5 of this Article notify the European Commission of the bodies which they have designated for carrying out the tasks pertaining to the conformity assessment to enable the European Commission to assign identification numbers to these bodies who may than be referred to as ‘notified bodies’.

Article 39

(1) The ministry shall carry out supervision of the operation of the notified bodies referred to in Article 38 paragraph 1 of this Article.

(2) Where the notified body ceases to meet the requirements laid down in Article 37 of this Act and the bylaws adopted pursuant to this Act, the minister shall withdraw the decision referred to in Article 38 paragraph 5 of this Act.

(3) The ministry shall notify the EU Member States and the European Commission on the withdrawal of the decision referred to in paragraph 2 of this Article.

Article 40

(1) The notified body shall perform its duties guaranteeing impartiality and within the competence assigned to it.

(2) The notified body shall not be the designer, manufacturer, supplier or user of the medical devices which are subject to conformity assessment.

(3) The staff of the notified body is bound to observe that there shall not be any conflict of interest which would result in favouring certain manufacturers and it is also bound to observe professional secrecy with regard to the medical device technical data and other information relating to the manufacturer.

(4) The notified body shall:

– notify the Agency on issued, modified or supplemented certificates on conformity within the time period which may not exceed 30 days from the day on which the certificate is issued;

– notify the Agency and the competent authorities in other EU Member States on suspended or withdrawn certificates of conformity, on applications for obtaining a certificate of conformity that have been rejected, and supply other information on the request of the competent authorities,

– withdraw the certificate of conformity where it establishes that the pertinent requirements are no longer met by the manufacturer or suspend the certificate of conformity as long as the appropriate corrective measures by the manufacturer have been taken, of which it shall inform the Agency,

– ensure the supervision and inspection activities of the ministry and supply all relevant information and documents.

(5) The Agency shall notify the European Commission and other EU Member States on the measures taken within the meaning of paragraph 4 subparagraph 3 of this Article.

VII Registration of medical devices into the register of medical devices

Article 41

(1) Registration of a medical device in the register of medical devices is an administrative procedure which is performed by the Agency within the protection of human health and with the objective to establish a list of medical devices which are available on the market in the Republic of Croatia.

(2) The registration of a medical device in the register of medical devices shall not be a condition for placing a medical device on the market.

(3) Any manufacturer of a medical device who has his registered place of business in the Republic of Croatia and any authorised representative of the manufacturer of the medical device with its registered place of business in the Republic of Croatia who place a medical device classified as Class I on the market shall inform the Agency and thereby apply for the registration of the medical device concerned in the register of the medical devices within the time period not exceeding 15 days from the day on which the medical advice was first placed on the market.

(4) The Agency shall decide on the registration of a medical device in the register of medical devices on the basis of a decision which must be adopted within a time period of 60 days from the day or receipt of the complete application.

(5) Against the decision referred to in paragraph 4 of this Article no appeal is allowed but the injured party may initiate an administrative dispute.

(6) The way in which the registration in the register of medical devices is carried out, modifications in the registration and the removal of a medical device from the register of medical devices, the content of the notification referred to in Article 42 of this Act and the necessary documentation that should be submitted shall be regulated by the minister in an ordinance.

Article 42

(1) Legal and natural persons who place on the market of the Republic of Croatia medical devices classified as Class IIa, IIb and III, *in vitro* diagnostic medical devices and active implantable medical devices shall notify the Agency thereof within a time period not exceeding 15 days from the day on which these products are placed on the market.

(2) On the request of the manufacturer of a medical device with its registered place of business in the Republic of Croatia, the Agency may issue a certificate certifying the conformity of the medical device or a family of medical devices concerned with the relevant rules in effect and declaring that the medical device in question is not subject to any restriction with regard to its placing on the market.

(3) The legal and natural persons referred to in paragraph 1 of this Article shall notify the Agency on any modifications of data and documentation relating to medical devices referred to in paragraph 1 of this Article.

Article 43

(1) After the medical device has been registered into the register referred to in Article 41 of this Act the registration holder shall notify the Agency any additional information and modification of the documentation on the basis of which the Agency has carried out the registration into the register.

(2) Where the additional information and modification of the documentation referred to in paragraph 1 of this Article requires modifications of the entry into the register, the Agency shall adopt a decision against which no appeal is allowed but the injured party may initiate an administrative dispute.

(3) The decision on modifications of the entry into the register referred to in paragraph 2 of this Article the Agency shall adopt or reject, depending on the nature of the modification concerned, within a time period not exceeding 30 days from the day of the receipt of the complete notification.

Article 44

(1) The Agency shall remove a medical device from the register of medical devices:

– on a substantiated request of the registration holder,

– on its own initiative where it finds that the medical device has been registered in the register of medical devices in contravention of the provisions of this Act and the bylaws adopted pursuant to this Act,

– based on other justified reason.

(2) The removal of the medical device from the register shall be based on the decision against which no appeal is allowed but an injured party may initiate an administrative dispute.

(3) The decision on removal of the medical device from the register shall be adopted by the Agency within a time period not exceeding 30 days.

(4) The fees related to the registration, rejection of registration, modification of information and removal of the medical device from the register of medical devices on the request of the registration holder, subject to a prior consent of the minister, shall be set by the Agency whereas the applicant or the registration holder shall bear the costs in question.

Article 45

(1) The documentation received by the Agency as well as all the data relating to medical devices, excluding the data which have been registered in the registers of the Agency, shall be covered by the business secrecy clause.

(2) The provision of paragraph 1 of this Article shall not apply to information exchange and warnings issued *vis-à-vis* the competent authorities and other states.

VIII Placing on the market of medical devices

Article 46

(1) Medical devices may be made available on the market in other words placed on the market and administered if they meet the essential requirements, if they have been issued a certification of conformity and if they have been affixed the CE marking.

(2) Any legal and natural person and public bodies who in any way come in the possession of medical devices must ensure the transport, storage and handling conditions in line with the relevant requirements.

(3) The Ordinance on good practice in the wholesale of medical devices shall be adopted by the minister.

Article 47

(1) The following persons may be engaged in the wholesale of medical devices:

– legal and natural persons with their place of business registered in the Republic of Croatia and who are registered in the wholesalers' register of medical devices of the Agency (hereinafter: wholesale distributors),

– legal and natural persons with their place of business registered in the European Union who meet the requirements relating to wholesale of medical devices in the Member State in which they have their seat.

(2) The manufacturers of medical devices may also be engaged in the wholesale of medical devices they manufacture and which meet all the requirements stipulated by this Act.

(3) Legal and natural persons engaged in the wholesale of exclusively medical devices referred to in Article 49 paragraph 3 of this Act do not have to be registered in the wholesalers' register of medical devices.

(4) The criteria and necessary documentation and data necessary for registration in the wholesalers' register of medical devices shall be regulated by the minister in an ordinance.

Article 48

Legal and natural persons engaged in the wholesale of medical devices shall carry out this activity observing the good practice in the wholesale of medical devices.

Article 49

(1) In the retail of medical devices shall be engaged the legal and natural persons who, in accordance with a separate law, have been authorised to carry out pharmacy activities and specialised retail stores selling medical devices who have been licenced by the Agency to carry out the activities involving the retail of medical devices.

(2) The legal and natural persons referred to in paragraph 1 of this Article may sell only the medical devices which meet all the requirements stipulated in this Act and which are considered appropriate to dispense medical devices taking into account their intended use and the environment in which the medical device concerned is intended to be used.

(3) Particular medical devices may be sold outside the pharmacy stores and specialised retail stores selling medical devices.

(4) The list of medical devices referred to in paragraph 3 of this Article shall be drawn up by the Agency and made available of the web site of the Agency.

(5) The Ordinance specifying the criteria for the retail in medical devices and the data necessary for the issuance of a licence to specialized retail stores selling medical devices shall be adopted by the minister.

Article 50

(1) Legal and natural persons engaged in pharmacy activity in the Republic of Croatia, specialized retail stores selling medical devices and wholesale distributors may offer for sale medical devices via Internet (distance selling) in line with their line of business and in compliance with the separate rules.

(2) Legal and natural persons performing pharmacy activities in the Republic of Croatia and specialized retail stores selling medical devices offering for sale medical devices via Internet shall communicate to the Agency the following data:

– the name and the permanent address of the point of sale from which it is engaged in the sales of medical devices,

– the date on which the sales activities started,

– the address of the web site used for the Internet sales and all relevant information necessary for the identification of the web site.

(3) The web site referred to in paragraph 2 of this Article used for the sale of medical devices must contain the following data:

– the name and the address of the company,

– the address of the point of sale of the medical devices,

– the name and surname of the owner or the relevant responsible person,

– the contact information of the Agency,

– the link to the web site of the Agency accompanied with the data on legal and natural persons engaged in the Internet sales of medical devices.

(4) The Ordinance specifying the criteria for the retail sales of medical devices via the Internet shall be adopted by the minister.

Article 51

(1) Legal and natural persons engaged in the import of medical devices from third countries shall import exclusively medical devices that meet all the requirements stipulated by this Act and for which the manufacturer has an authorised representative in the European Union.

(2) The import of medical devices shall be carried out by legal and natural persons who have been registered in the wholesalers' register of medical devices.

Article 52

Legal and natural persons engaged in the import of medical devices shall be responsible to:

– ensure that the manufacturer has carried out the appropriate conformity assessment procedure relating to the imported medical device,

– ensure that the manufacturer has prepared the proper technical documentation on the imported medical device,

– identify the contact name and the contact permanent address on the device, packaging or in the technical documentation attached to the device concerned,

– be in the possession of the declaration of conformity at the point of impost and, if necessary, keep available for inspection other relevant documentation certifying the conformity of the medical device concerned.

Article 53

(1) The Agency shall register a wholesale distributor in the wholesalers' register of medical devices and issue the licence for the retail of medical devices in a specialized store within a time period of 60 days from the day of the receipt of a complete application.

(2) Where the application is incomplete, in other words, if the application is not supplemented by the requested data and documentation, the Agency shall by means of a procedural order request the applicant to rectify the problem within a time period not exceeding 30 days.

(3) Where the Agency requests that the applicant should supply additional data to its application, the time period referred to in paragraph 1 of this Article shall not run from the day of the receipt of the additional data. The time period shall also not run during the time which has been granted to the applicant to provide a written or oral explanation.

(4) The registration in the wholesalers' register of medical devices and the licence for the retail of medical devices referred to in paragraph 1 of this Article shall be based on the decision against which no appeal is allowed but the injured party may initiate an administrative dispute.

(5) The fees relating to the registration, modifications of the registration and removal from the wholesalers' register of medical devices as well as the fees for issuing, modifications or withdrawal of the licences referred to in paragraph 1 of this Article, subject to a prior consent of the minister, shall be laid down by the Agency whereas the applicant or the registration holder or the permit holder shall bear the costs in question.

Article 54

(1) The Agency shall remove the wholesale distributor from the wholesalers' register of medical devices or withdraw the licence for the retail of medical advices granted to a specialised store where it finds that the registration holder or licence holder no longer meets the criteria on the basis of which the registration in the register has been carried out or where the issued licence no longer meets the criteria concerned.

(2) On the basis of a written request submitted by the registration holder or the licence holder the Agency shall by means of a decision remove the wholesale distributor from the wholesalers' register of medical devices or withdraw the licence referred to in paragraph 1 of this Article, if the registration holder or the licence holder ceases to perform the activity concerned.

(3) The entry into the wholesalers' register of medical devices and the licence for the retail of medical devices in a specialised store shall be withdrawn and removed from the register by means of a decision against which no appeal is allowed but the injured party may initiate an administrative dispute.

Article 55

(1) The registration holder registered in the wholesalers' register of medical devices or the licence holder for the retail of medical devices in a specialised store shall inform the Agency in writing of any modifications in respect with the criteria, documentation and information on the basis of which the registration in the wholesalers' register has been carried out or on the basis of which the licence has been issued.

(2) Where the additional data and modifications of the documentation referred to in paragraph 1 of this Article give rise to the modifications of the entry into the wholesalers' register or the licence referred to in paragraph 1 of this Article, the Agency shall adopt the decision thereof within 30 days from the day of the receipt of a complete application.

(3) Where the application is incomplete, in other words, if the relevant data and documentation have not been delivered in the supplement of the application, the Agency shall by means of a procedural order request the applicant to rectify the problem within a time period not exceeding 15 days from the receipt of the procedural order.

(4) If the Agency requires from the applicant additional data the time period referred to in paragraph 2 of this Article shall not run until the day the additional data to the application have been submitted. The time period shall also not run during the time period granted to the applicant for submittal of an oral or written explanation.

(5) The modifications to the entry into the wholesalers' register of medical devices or to the licence for the retail of medical devices in a specialised store shall be authorised on the basis of a decision against which no appeal is allowed but the injured party may initiate an administrative dispute.

Article 56

(1) The Croatian Institute for Health Insurance shall adopt the basic and the additional list of medical devices covered by the compulsory health insurance which is drawn up in compliance with a separate law.

(2) The criteria for the inclusion of the medical devices in the lists referred to in paragraph 1 of this Article shall be determined by the minister.

(3) The criteria for the pricing of medical devices referred to in paragraph 1 of this Article shall be regulated by the minister in an ordinance.

Article 57

Medical devices which are no longer intended for use shall be considered waste and are subject to application of waste management rules.

Article 58

(1) The Agency shall charge an annual fee for the decision on entry into the register of the manufacturers of medical devices, the decision on issuance of the retail licence and the decision on the registration in the wholesalers' register of medical devices.

(2) The level of the annual fee referred to in paragraph 1 of this Article shall be determined by the Agency, subject to the prior consent of the minister. The annual fee shall be paid by the registration holder or the licence holder.

IX Advertising of medical devices

Article 59

(1) Advertising of medical devices within the meaning of this Act shall mean any activity designed to promote the prescription, sale or consumption of a medical device, in any written or oral form, using picture and sound, in electronic, digital or other form.

(2) It shall be prohibited to advertise any medical device which does not meet the requirements laid down by this Act, with the exception of the medical devices intended to be used in exhibitions, demonstrations, fairs etc. Such devices must be provided a visible sign clearly indicating that they cannot be marketed or put into service.

(3) Misleading advertising of medical devices shall be prohibited.

(4) Medical devices which are intended for use exclusively by healthcare practitioners may be advertised but the advertising in such a case must be targeted exclusively to a healthcare professionals.

Article 60

Advertising of medical devices shall ban any information which:

– gives the impression that a medical device can guarantee recovery from the illness and that the health of the subject can be enhanced exclusively by using the advertised medical device, whereas the objective judgement must be furnished by evidence,

– suggests that the health of the subject could be affected by not using the medical device that has been advertised;

– encourage the patients to abandon the generally accepted treatment procedures;

– is directed exclusively or principally at children;

– confuse by the use of scientific terms unknown to the general public for common health conditions;

– refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing but who, because of their celebrity, could encourage the use of the medical device;

– suggests that the safety of the medical device is due to the fact that it is natural;

– could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;

– refers, in improper, alarming or misleading terms, to claims of recovery;

– refers, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease;

– assaults human dignity.

X Vigilance

Article 61

(1) A health practitioner, manufacturer or authorised representative of the manufacturer and legal and natural persons engaged in the wholesale or imports of the medical devices shall inform the Agency in writing on any adverse incidents relating to medical devices:

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

- any technical or medical reason in relation to the characteristics or performance of a medical device for the reasons referred to in subparagraph 1 of this paragraph, leading to a recall of the medical device by the manufacturer.

(2) The persons referred to in paragraph 1 of this Article shall report an adverse incident to the Agency:

1. where there is a serious threat to public health: immediately, but not later than two calendar days after awareness of this event;

2. where death or unanticipated serious deterioration in state of health occurred: immediately after the link between the medical device and the incident has been established, but not later that ten calendar days elapsed following the date of awareness of the event;

3. others: immediately after the link between the medical device and the event has been established but not later than 30 calendar days elapsed following the date of awareness of the event.

(3) Where the Agency receives information on an adverse event from a health practitioner, medical institution or wholesale distributor, it shall without delay inform of the incident the manufacturer or the authorised representative of the manufacturer.

(4) The manufacturer or the authorised representative of the manufacturer of the medical device shall inform the Agency in writing on any corrective measures he intends to implement so as to reduce to a minimum the possibility of reoccurrence of the adverse event.

(5) After having carried out the analysis of the adverse event the Agency shall inform the European Commission and the EU Member States of the measures implemented so as to reduce to a minimum the possibility of reoccurrence of the adverse event.

Article 62

The manufacturer or the authorised representative of the manufacturer of the medical devices shall:

1. appoint a responsible reference person for vigilance of medical devices who shall be permanently available,

2. establish and maintain its own vigilance system for medical devices ensuring the collection, evaluation and dissemination of data relating to adverse events in respect of medical devices and cooperate with the Agency,

3. within an appropriate scope keep a detailed record on all adverse events that have taken place in the Republic of Croatia and other states.

Article 63

(1) Where a health practitioner takes part in a clinical investigation as an investigator he shall immediately notify the holder of the clinical trial authorisation of any adverse event or suspected adverse event relating to medical devices, except in the case of adverse events for which this is not required in line with the clinical investigation plan (protocol) and investigator's instructions.

(2) The holder of the clinical trial authorisation shall:

1. keep a detailed record of all adverse events notified to him by the investigator, and submit the information on request to the Agency and the Central Ethics Committee,

2. report to the Agency all adverse events that have resulted in death or serious deterioration of the health status of the users immediately after the link between the medical device and the incident has been established, but not later than ten calendar days elapsed following the date of awareness of the event,

3. report to the Agency any adverse events that could have but did not result in death or that could have but did not lead to serious deterioration of the health status of users due to favourable circumstances, immediately after the link between the medical device and the incident has been established, but not later than 30 calendar days elapsed following the date of awareness of the event,

4. notify the investigators of any adverse events referred to in items 2 and 3 of this paragraph that occurred during the clinical trial of the medical device.

Article 64

(1) Where there is a suspicion of a counterfeit medical device the persons referred to in Article 61 paragraph 1 of this Act shall inform the Agency of their suspicion within 24 hours.

(2) The surveillance reporting system relating to adverse events of medical devices shall be regulated by the minister in an ordinance.

Article 65

The Agency may request the manufacturer to provide a report on the experience acquired during the use of a new *in vitro* diagnostic medical device referred to in Article 3 point 7 of this Act during a time period of two years from its placing on the market.

XI Supervision

Article 66

(1) Supervision of the implementation of provisions of this Act and the bylaws adopted on the basis of this Act shall be carried out by the Ministry.

(2) The pharmaceutical inspections regarding the implementation of the provisions of this Act and the bylaws adopted on the basis of this Act shall be performed by pharmaceutical inspectors of the Ministry.

Article 67

In carrying out the inspections the pharmaceutical inspector shall have the following rights and duties:

– to inspect the business premises, facilities, installations, devices and equipment,

– to inspect the contracts, records, notes and other documents. If these documents are in electronic form, the inspector may request access to the files concerned and their printed versions,

– to seize the copies of certain documents stating so in the inspection report,

– to require any necessary information from the manufacturer, registration holder, wholesale distributor or importer and inspect the documentation on conformity and the technical documentation on the medical device concerned,

– to sample the medical device concerned,

– to inspect personal identification documents in order to identify the persons concerned,

– with the view to adducing evidence, to take photographs or record on any other visual media the data concerning the person, the premises, the facilities, the installations, the accessory and other referred to in the first subparagraph of this paragraph,

– to order particular inspections and investigations relating to the medical device after it has been placed on the market or put into service,

– to order the recall of the medical device from the market or from the service,

– to order proper labelling of the medical device,

– to order the medical device which does not meet the statutory requirements to be properly disposed where this is necessary for the protection of health of humans,

– to order legal and natural persons the performance of the activity in conformity with the criteria set out by this Act and other rules,

– to order rectification of established irregularities and deficiencies with a set time period,

– to order the implementation of other measures in accordance with the powers stipulated under this Act and other rules,

– to order suspension or termination of a clinical trial where the latter has not been carried out in conformity with the provisions of this Act and the ordinance adopted pursuant to this Act,

– to restrict or suspend placing on the market or putting into service, in other words prohibit the use of a medical device which is not in conformity with the requirements stipulated by the provisions of this Act and other rules adopted pursuant to this Act,

– to temporarily prohibit placing on the market, putting into service or advertising of the medical device where there is reasonable doubt regarding the conformity of the medical device with statutory requirements,

– to prohibit placing on the market and putting into service of a medical device where there has been suspected that the medical device or the documentation has been counterfeited,

– to prohibit the natural or legal person distance sale of the medical devices via the Internet where it does not meet the requirements stipulated under this Act,

– to temporarily prohibit the operation of a legal and natural person where they do not meet the requirements stipulated under this Act and the rules adopted pursuant to this Act,

– to prohibit the operation of the legal and natural person where they are engaged in conformity assessment, manufacturing, designing and placing on the market without the authorisation of the minister, in other words, without having been licenced to do so by the Agency,

– to prohibit advertising of a medical device which is in contravention of the provisions of this Act,

– to prohibit the carrying out of the activities which are in contravention of this Act and other rules.

Article 68

(1) Where the pharmaceutical inspector in the process of carrying out inspections referred to in Article 67 subparagraph 5 of this Act decides to ask for verification of a medical device, the verification costs shall be borne by the natural or legal person which has placed the medical device on the market or put the device concerned into service.

(2) The Agency may carry out verification of a particular medical device under the relevant rules established by the Croatian Pharmacopoeia and the European Pharmacopoeia.

Article 69

The jobs of the pharmaceutical inspector may be performed by a person who holds an undergraduate and graduate university degree or an integrated undergraduate and graduate university degree in health care or any related studies, who has three years of work experience in the relevant jobs and who has passed the state licence exam.

Article 70

Where the pharmaceutical inspector does not have necessary vocational training, knowledge or necessary equipment for carrying out the inspection or verification of a medical device, in other words, for carrying out particular operations within the process of inspection, for the performance of these jobs relating to the performance of pharmaceutical inspections for which special vocational training is required, the minister shall appoint adequate experts.

Article 71

(1) A pharmaceutical inspector shall be issued an identity card proving his official status, identity and powers.

(2) The shape and the content of the identity card and the criteria for the issuance and keeping the register of the issued identity cards shall be regulated by the minister in an ordinance.

Article 72

Where during the inspection the pharmaceutical inspector finds that the infringement has been committed that constitutes a minor offence or a criminal offence, he shall without delay, within a time period not exceeding 15 days from the day on which the inspection is completed, make a request to open proceedings and notify thereof the relevant authority.

Article 73

The legal and natural persons shall ensure the undisturbed performance of the inspection by the pharmaceutical inspector and on his request make available the necessary quantity of samples for verification as well as other necessary data and information.

Article 74

(1) In carrying out the inspection the pharmaceutical inspector shall inspect the business premises, facilities, devices, equipment and documentation.

(2) In carrying out the inspections referred to in paragraph 1 of this Article the pharmaceutical inspector shall have the right to inspect:

– the contracts, records, notes and other quality system documents as well as other documentation. If the documentation is in electronic form, the inspector may request access to the files concerned and the printed versions of the documents concerned,

– get hold of the copies of the documents stating so in the inspection report,

– free of charge take samples of medical devices raw materials and component parts with the view to quality testing,

– free of charge get hold of and use the data from the official records and other databases relating to the persons, if this is necessary for the performance of the inspection,

– recall or withdraw from the market the medical devices which are not in conformity with the provisions of this Act,

– inspect the personal identification documents with the view to establishing of the identity of the persons concerned,

– take photographs or record using any other visual media the data relating the person, the premises, the facilities, the installations, the accessory and other referred to in paragraph 1 of this Article with the view adducing evidence.

(3) The pharmaceutical inspector may undertake an inspection visit at any time without any prior notice.

Article 75

If a pharmaceutical inspector receives physical resistance, he may ask to work with a law enforcement official.

Article 76

The pharmaceutical inspector may undertake an inspection also on the request of the Agency or the European Commission, within the territory of the Republic of Croatia, other EU Member States or third countries.

Article 77

(1) In carrying out inspections the pharmaceutical inspector shall act in line with the rules relating to professional secrecy and confidentiality of data.

(2) The legal and natural person shall inform the pharmaceutical inspector on the data covered by the obligation of professional secrecy and the applicable degree of confidentiality.

Article 78

(1) The pharmaceutical inspector shall take an oral decision in the following cases:

1. where the threat to human health or life of humans is such that it requires a certain measure to be taken without delay,

2. where there is a threat that the evidence may be concealed, altered or destroyed, unless the measure is taken immediately.

(2) The pharmaceutical inspector may order the execution of the oral decision immediately. The decision on the inspection carried out shall be entered into the inspection report.

(3) The pharmaceutical inspector shall make a written copy of the decision within a time period of eight days form the adoption of the oral decision.

Article 79

Against the decision of the pharmaceutical inspector no appeal is allowed but the injured party may initiate an administrative dispute.

Article 80

(1) The pharmaceutical inspector shall make a report of the control inspection, established facts, undertaken or ordered measures and activities carried out during the inspection

(2) The copy of the inspection report shall be communicated by the pharmaceutical inspector to the natural or legal person who has been subjected to inspection.

Article 81

The procedures of the pharmaceutical inspector shall fall under the scope of the provisions of the General Administrative Procedures Act.

Article 82

(1) The pharmaceutical inspector shall keep the register of performed control inspections.

(2) The method of keeping the register shall be regulated by the minister in an ordinance.

Article 83

The pharmaceutical inspector shall be held responsible:

1. if in the course of the inspection he fails to undertake or impose measures he was obliged to undertake or impose,

2. if he exceeds its powers,

3. if he does not make a request to open proceedings or does not notify the established irregularities or deficiencies to the competent authorities.

XII Penalty clause

Article 84

(1) A fine in the amount ranging from HRK 70.000,00 to 100.000,00 shall be imposed on a legal and natural person if they:

1. place on the market medical devices systems or groups in contravention of Article 16 paragraphs 1 and 3 and Article 17 paragraphs 1, 3, 4, 6 and 7 of this Act,

2. conduct a clinical investigation of a medical device without the authorisation of the minister (Article 2 paragraph 2),

3. starts a clinical investigation without an informed consent of the person subject to the clinical trial concerned (Article 23),

4. conduct a clinical investigation in contravention of Article 23 paragraphs 2, 3 and 5 of this Act,

5. conduct a clinical investigation in contravention of the provision of 24 paragraph 1 of this Act,

6. do not meet the requirements referred to in Article 27 paragraph 1 of this Act,

7. should the manufacturer of medical devices not be insured against harmful effects which might occur by the user of medical device (Article 27 paragraph 2),

8. do not carry out the compatibility assessment procedure relating to the medical device on the basis of the classification and risk imposed by the medical device concerned (Article 31 paragraph 2),

9. place a medical device on the market in contravention of the provision of Article 32 paragraph 1 of this Act,

10. label the medical device in contravention of the provision of Article 33 paragraphs 1 and 2 of this Act,

11. affix a CE marking on the medical device which does not meet the requirements laid down by this Act (Article 33 paragraph 3),

12. label a product which is not a medical device with the CE marking (Article 33 paragraph 4),

13. put any signs or imprints on the medical device which could be misleading (Article 33 paragraph 5),

14. perform the activity relating to conformity assessment without the authorisation of the minister (Article 36 paragraph 1),

15. perform the jobs partially and outside their competence (Article 40 paragraph 1),

16. act against the provision of Article 40 paragraphs 2 and 3 of this Act,

17.place on the market or put into service a medical device in contravention of the provision of Article 46 paragraph 1 of this Act,

18. do not ensure transport, storage and handling conditions of medical devices within the meaning of the statutory requirements (Article 46 paragraph 2),

19. engage in the wholesale of medical devices in contravention of the provision of Article 47 paragraphs 1 and 2 of this Act,

20. engage in the wholesale of medical devices but fail to meet the statutory requirements (Article 48 paragraph 1),

21. engage in the retail of medical devices in contravention of Article 49 paragraphs 1, 2 and 3 of this Act,

22. engage in distance selling of the medical devices via the Internet in contravention of the provision of Article 50 paragraphs 2 and 3 of this Act,

23. engage in the import of the medical devices from third countries in contravention of the provisions of Articles 51 and 52 of this Act,

24. dispose of medical devices no longer in use in contravention of the provisions of Article 57 of this Act,

25. advertise about the medical device in contravention of the provision of Article 59 paragraphs 2, 3 and 4 of this Act,

26. if the advertisement on medical device contains information referred to in Article 60 paragraph 1 of this Act,

27. do not notify the Agency on an adverse event and undertaken corrective actions under Article 61 of this Act,

28. fail to meet the requirements relating to vigilance of medical devices (Article 62),

29. fail to notify the adverse events in clinical investigations (Article 63),

30. do not ensure the pharmaceutical inspector to carry out the inspection within the meaning of the provisions of this Act and the rules adopted pursuant to this Act (Article 73),

31. do not act within the meaning of the enforceable decision of the pharmaceutical inspector on the basis of which the imposition of certain measures and actions has been ordered or the operation has been prohibited (Article 79).

(2) For the minor offence referred to in paragraph 1 of this Article the responsible person in the legal person shall also be fined the amount ranging from HRK 7.000,00 to 10.000,00.

Article 85

(1) A fine in the amount ranging from HRK 50.000,00 to 80.000,00 shall be imposed on a legal and natural person if they:

1. place a medical device on the market or put a medical device into service without the instruction for use or where the instruction for use or the labelling contravene the provisions of this Act (Article 12 paragraphs 1, 2, 4, 5 and 6),

2. do not notify the ministry on any modification of the documentation or the clinical trial procedure on the basis of which the clinical investigation has been authorised (Article 22 paragraph 1),

3. do not carry out the clinical investigation within the meaning of Article 26 paragraph 3 of this Act,

4. do not file an application for the registration in the manufacturers register of the Agency (Article 28 paragraph1),

5. do not notify the Agency on the modifications or additional material supplemented to the documentation on the basis of which the Agency made the entry into the register (Article 29 paragraph 1),

6. do not communicate the information referred to in Article 40 paragraph 4 subparagraphs 1 and 2 of this Act,

7. do not file the application for registration in the register of medical devices of the Agency (Article 41 paragraph 3),

8. do not notify the Agency on the modifications and additional information supplemented to the documentation on the basis of which the Agency made the entry into the register (Article 43 paragraph 1),

9. do not file the application for the modification of the entry into the wholesalers' register of medical devices or for the modification of the licence for the retail of medical devices (Article 55 paragraph 1),

10. do not notify the suspicion of a counterfeit medical device (Article 64 paragraph 1).

(2) For the minor offence referred to in paragraph 1 of this Article the responsible person in the legal person shall also be fined the amount ranging from HRK 5.000,00 to 8.000,00.

XIII Transitional and final provisions

Article 86

The ordinances referred to in Article 6 paragraph 3, Article 9 paragraph 6, Article 13 paragraph 2, Article 20 paragraph 1, Article 21 paragraph 6, Article 24 paragraph 1, Article 30 paragraph 5, Article 35, Article 36 paragraph 2, Article 41 paragraph 6, Article 46 paragraph 3, Article 47 paragraph 4, Article 49 paragraph 5, Article 50 paragraph 4, Article 56 paragraphs 2 and 3, Article 64 paragraph 2, Article 71 paragraph 2 and Article 82 paragraph 2 of this Act, shall be adopted by the minister, in accordance with the authority assigned to him within the meaning of this Act, within a time period of one year from the entry into force of this Act.

Article 87

Until the entry into force of the ordinances referred to in Article 86 of this Act the following ordinances shall remain in force:

1. Ordinance on clinical investigations and good clinical practice (Official Gazette, no. 121/07), in the part thereof relating to medical devices,

2. Ordinance on the criteria for issuing permits to specialised stores for retail of medicinal products and medical devices (Official Gazette, no. 29/05, 81/06 and 5/07), in the part thereof relating to medical devices,

3. Ordinance on adverse events reports relating to medical devices (Official Gazette, no. 74/09),

4. Ordinance on essential requirements, classification, quality system, entry into the register of manufacturers and register of medical devices and on conformity assessment of medical devices (Official Gazette, no. 43/10),

5. Ordinance on good practice and criteria for granting a licence for placing of the medical devices on the market (Official Gazette, no. 54/05 and 81/06),

6. Ordinance on good practice, criteria for granting a licence for the wholesale and import and export of medical devices (Official Gazette, no. 38/10),

7. Ordinance on the criteria for the inclusion of orthopaedic and other devices on the List of devices of the Croatian Institute for Health Insurance (Official Gazette, no. 138/09 and 43/13),

8. Ordinance on the criteria for pricing of orthopaedic and other devices (Official Gazette, no. 138/09 and 29/12).

Article 88

(1) The decisions on the registration of the manufacturers with their registered place of business in the Republic of Croatia in the register of manufacturers of medical devices which have been issued before the adoption of this Act shall remain in effect.

(2) On the day of entry into force of this Act the Agency shall initiate proceedings to repeal decisions on the registration of the manufacturers - representatives of foreign manufactures in the register of manufacturers of medical advices issued before the entry into force of this Act.

Article 89

(1) The decisions on the registration of medical devices of Class I in the register of the medical devices, which have been manufactured by the manufacturers with their registered place of business in the Republic of Croatia issued before the entry into force of this Act shall remain in effect.

(2) For the medical devices of Class IIa, IIb and III, *in vitro* diagnostic medical devices and active implantable medical devices that have been registered in the register of medical devices of foreign manufacturers and manufacturers with the registered place of business in the Republic of Croatia until the entry into force of this Act, it shall be considered that they have been placed on the market in the territory of the Republic of Croatia in compliance with Article 42 paragraph 1 of this Act, if they meet the requirements laid down by this Act.

Article 90

The manufacturing licences issued on the basis of the rules that have been in effect before this Act enters into force shall remain valid until the date of their expiration.

Article 91

(1) Medical devices that have been licenced for the wholesale of medical devices on the basis of the rules in effect before this Act enters into force shall be considered as having been registered in the wholesalers' register of medical devices in line with this Act.

(2) Licences for the retail of medical devices issued on the basis of the rules in effect until the entry into force of this Act shall remain applicable also after the entry into force of this Act.

Article 92

Legal persons performing the activities of import and export of medical devices on the day of entry into force of this Act shall bring their operations in compliance with the provisions of this Act within a time period not exceeding 90 days from the day of entry into force of this Act.

Article 93

The Medical Devices Act (Official Gazette, no. 67/08 and 124/11) shall cease to be in effect on the day on which this Act enters into force.

Article 94

This Act shall enter into force on the eighth day from the day of its publication in Official Gazette, with an exception of Articles 1 to 5, Article 6 paragraphs 1 and 2, Articles 7 and 8, Article 9 paragraphs 1 to 5, Articles 10 to 12, Article 13 paragraph 1, Articles 14 to 29, Article 30 paragraphs 1 to 4, Articles 31 to 34, Articles 36 to 40, Article 41 paragraphs 1 to 4, Articles 42 to 63, Article 64 paragraph 1, and Articles 65 to 93, which shall enter into force on the day of the accession of the Republic of Croatia to the European Union.

Class: 022-03/13-01/123

Zagreb, 14 June 2013

CROATIAN PARLIAMENT

President of the
Croatian Parliament

Josip Leko, m. p.