

268/2014 Coll.

ACT

of 22 October 2014

on Medical Devices and on Amendments to Act No [634/2004 Coll.](#), on Administrative Fees, As Amended

The Parliament adopted the following act of the Czech Republic:

PART ONE

MEDICAL DEVICES

TITLE I

INTRODUCTORY PROVISIONS

Section 1

Subject matter

This Act incorporates relevant regulations of the European Union (hereinafter referred to as the “Union”)¹⁾ and defines the handling of medical devices and their accessories.

Basic provisions and definition of terms

Section 2

(1) A medical device shall mean any instrument, apparatus, appliance, software, including software intended by the manufacturer for specific use for diagnostic or therapeutic purposes and necessary for the correct use of the medical device, material or other article, intended by the manufacturer to be used for human beings for the purposes of:

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

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

(2) Upon compliance with the general definition referred to by paragraph 1, a medical device shall mean, in particular:

- a) an active implantable medical device;
- b) an *in vitro* diagnostic medical device;
- c) a custom-made medical device;
- d) a product intended for the administration of a pharmaceutical, except for products placed on the market in a manner safeguarding that the medical device and the pharmaceutical form a single integral product intended solely for single use in this combination; such product shall be considered a

medicinal product;

e) a product containing as its integral part a substance which, when used independently, may be considered a medicinal product, if its effect provides only an add-on effect to the effect of the medical device; and

f) a product containing as its integral part a substance which, when used independently, may be considered an ingredient of a medicinal product or a medicinal product derived from human blood or plasma, if its effect provides only an add-on effect to the effect of the medical device.

(3) A medical device shall not mean

a) a medicinal product;

b) human blood and products derived therefrom, human blood plasma, blood cells of human origin and a device containing at the time of its placement on the market such product derived from blood, blood plasma or cell, except for products referred to by [Section 2, paragraph 2, letter f\)](#);

c) a transplant, tissue or cell of human origin, a product derived therefrom, and a product containing tissue or cell of human origin, except for products referred to by [Section 2, paragraph 2, letter f\)](#);

d) a transplant, tissue or cell of animal origin, except for medical devices manufactured using non-live animal tissue or non-live product derived from animal tissue;

e) a dietary supplement;

f) a cosmetic product; and

g) a biocidal product.

(4) An active medical device shall mean a medical device the operation of which depends on a source of electrical or other energy which is not supplied directly by the human organism or gravitation.

(5) An active implantable medical device shall mean an active medical device intended for complete or partial insertion in the human organism which is to stay on-site following its insertion. An accessory of an active implantable medical device shall be considered part thereof.

(6) An *in vitro* diagnostic medical device shall mean a 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 anomaly, to determine the safety and compatibility with potential recipients, or to monitor therapeutic measures. Vacuum-type or other types of specimen receptacles, specifically intended by the manufacturer for the primary containment and preservation of samples obtained from the human body for the purposes of *in vitro* diagnostic examination shall be also considered *in vitro* medical devices. Products for general laboratory use shall not be *in vitro* medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer for *in vitro* use.

(7) A medical device for self-testing shall mean an *in vitro* diagnostic medical device Intended by the manufacturer to be able to be used by persons who are not necessarily healthcare professionals in a home environment.

Section 3

(1) A custom-made medical device shall mean a medical device intended for a single specific patient only, if manufactured according to an individual design of its model characteristics designed

by a medical professional of proper expert and specialised qualification. A mass-produced medical device requiring to be adapted to meet the special requirements of a qualified medical professional shall not be considered custom-made medical devices.

(2) A medical device intended for clinical investigation shall mean any device intended for use by a duly qualified medical practitioner exclusively for the conduct of its own efficacy and safety in the course of a clinical investigation in adequate human clinical environment.

(3) A medical device intended for performance evaluation shall mean any *in vitro* diagnostic medical device intended by the manufacturer to be subject to one or more performance evaluation studies conducted in clinical laboratories outside the premises of the manufacturer.

(4) A single use device shall mean a device intended by the manufacturer to be used once only for a single patient.

(5) Medical device accessory shall mean an article which whilst not being a medical device, is intended by the manufacturer to be able to be used together with a device to enable that device to be used in accordance with its intended purpose. Sampling devices which are directly applied to the human body for the purposes of obtaining a specimen shall not be considered accessories of an *in vitro* diagnostic medical device.

(6) A medical device variant shall mean a closer specification of a particular model or packaging of a medical device. Individual variants of a medical device differ, in particular, in size, number of pieces in a packaging, colour versions, or source of power. Individual variants of a medical device shall have an identical commercial name, intended purposes, risk class, material composition and manufacturing process.

Section 4

(1) Handling of medical devices shall mean its:

- a) manufacture, including conformity assessment;
- b) placement on the market;
- c) import;
- d) distribution;
- e) putting into service;
- f) dispensing;
- g) sale;
- h) use in the provision of healthcare services;
- i) servicing; and
- j) disposal.

(2) Placing on the market shall mean the first making available of the medical device other than a device intended for clinical investigation or for performance evaluation for it to be distributed or used on the market of the Union Member States, states forming the European Economic Area, Switzerland, and Turkey (hereinafter referred to as the "Member State"), regardless of whether it is new or fully refurbished.

(3) Import shall mean the placement of the medical device on the market if procured outside the territory of the Member States.

(4) Distribution shall mean the delivery of a medical device on the market, if procured within the territory of the Member States; distribution shall not mean the provision of a medical device to the consumer who does not process it any more or provide services to third parties using such device.

(5) Putting into service shall mean the time point at which the medical device is first ready for use for the intended purpose within the territory of the Member States. For active implantable medical devices, this time point shall mean their provision to a medical professional for implantation.

(6) Conformity assessment shall mean the process conducted in compliance with another legal regulation governing the technical requirements for products.

(7) Except for handling referred to in paragraph 1) letter a), a medical device may be handled only if conformity assessment has been completed for the medical device.

Section 5

For the purposes of this Act

a) dispensing shall mean the provision of a medical device prescribed by a doctor's prescription by the dispensing person to the patient; dispensing shall include the provision of information necessary for proper and safe use and basic maintenance of the dispensed medical device;

b) sale shall mean the provision of the medical device to the user, including sale by mail, unless dispensing is concerned;

c) manufacturer shall mean a person safeguarding the design, manufacture, packaging and labelling of a medical device prior to its placement on the market, under its own name, business or company name, regardless of whether such person conducts these activities by themselves or via a third person; the obligations of a manufacturer shall apply also to a person who assembles, packs, adapts, refurbishes or labels one or more finished products or assigns the intended purpose thereto, with the intention to place the medical device on the market under the person's own name.

d) an authorised representative shall mean a person established in a Member State who has been explicitly authorised by the manufacturer to act on behalf of the latter and who may be addressed by the state administration authorities of the Member States regarding the manufacturer's obligations instead of the manufacturer;

e) an importer shall mean a person established in a Member State who places the medical device on the market, if procured outside the territory of the Member States;

f) a distributor shall mean a person in the supplier chain, except for the manufacturer or importer, who supplies the medical device procured outside the territory of the Member States to the market;

g) a dispensing person shall mean a person operating a pharmacy, a medical device dispensary, or an optician's shop; a person dispensing a medical device which is fully or partially reimbursed by the public health insurance may also be another person with whom the health insurance company has concluded a contract on dispensing in compliance with the act governing public health insurance (hereinafter referred to as the Dispensing contractor");

h) a notified body shall mean a person who has been notified by a Member State to the Union authorities and other Member States as a person authorised for activities in conformity assessment of medical devices;

i) the intended purpose shall mean the use for which the medical device is intended according to the data specified by the manufacturer on the labelling, in the instructions for use or in promotional materials of the medical device;

j) withdrawal from the market shall mean a measure the objective of which is to prevent a medical

device present in the supplier chain from being supplied to the territory of the Czech Republic;

k) a recall shall mean a measure the purpose of which is to return the medical device to the person who placed the medical device on the market, supplied, dispensed or sold the medical device if the medical device has already been supplied to the user;

l) instructions for use shall mean the information provided by the manufacturer in order to inform the user of the medical device about its safe and proper use, its expected efficacy, and on any precautions which have to be taken; the information which has to be specified in the instructions for use is set forth by an implementing legal regulation;

m) a side effect shall mean any adverse concurrent phenomenon which has been identified during or after the use of the medical device in compliance with its intended purpose;

n) an interaction shall mean an undesirable effect between medical devices or between a medical device and a medicinal product or a medical device and other objects during use compliant to their intended purpose.

Section 6

Medical device classification

(1) Medical devices are classified by the degree of the risk of the proper use of the concerned medical device for health

a) to risk classes I, IIa, IIb, or III, in ascending order by the degree of risk of the proper use of the concerned medical device for health, unless active implantable medical devices and *in vitro* diagnostic medical devices are concerned; the rules for inclusion in the aforementioned classes are stipulated by an implementing legal regulation;

b) where *in vitro* diagnostic medical devices are concerned, to medical devices included in List A and in List B, medical devices intended for self-testing, and other *in vitro* diagnostic medical devices; List A and B are stipulated by an implementing legal regulation.

(2) Furthermore, medical devices are classified by generic groups. A medical device generic group shall mean a set of medical devices of the same or similar intended purpose or common technology which allows for their generic classification, regardless of the properties of a specific medical device. Generic groups are set forth by an implementing legal regulation.

TITLE II

EXECUTION OF STATE ADMINISTRATION

Section 7

Concerned state administration authorities

State administration referred to by this Act shall be executed by

a) the Ministry of Health (hereinafter referred to as the “Ministry”); and

b) the State Institute for Drug Control (hereinafter referred to as the “Institute”).

Section 8

Ministry

In the area of medical devices, the Ministry shall

a) issue binding positions on a person’s application for change, suspension or revocation of authorisation referred to by the act governing technical requirements for products, if the authorisation applies to activities in conformity assessment of medical devices;

- b) decide on temporary withdrawal from the market of a medical device which, despite being properly CE-marked, correctly installed, maintained and used in compliance with its intended use may jeopardise the health or safety of users and other persons, as applicable;
- c) safeguard
 1. cooperation with concerned authorities of the Member States and of the Union in the area of medical devices, including representation in working groups and committees of the aforementioned authorities within the scope of its powers,
 2. cooperation with the concerned authorities of foreign states, with the World Health Organisation, with state authorities responsible for occupational safety and health;
- d) cooperate with the Institute, the Czech Office for Standards, Metrology and Testing, with notified bodies and other authorities and persons involved in the handling of medical devices;
- e) grant exemptions referred to in [Section 99](#); and
- f) maintain the Registry of Medical Devices.

Section 9 Institute

In the area of medical devices, the Institute shall:

- a) decide on whether a medical device is concerned and on its classification, either upon request, or ex-officio;
- b) authorise manufacturers, authorised representatives, importers, distributors, persons conducting service, sponsors of clinical investigations, and notified bodies;
- c) notify medical devices;
- d) administer the National Medical Device Information System;
- e) via the Registry of Medical Devices, in a manner allowing for remote access, publish
 1. information about registered persons handling medical devices,
 2. information about notified medical devices, and
 3. information provided by the manufacturer, the authorised representative of the distributor in respect of measures aimed at the minimisation of recurrence of adverse incidents referred to by [Section 74, paragraph 2](#);
- f) safeguard the provision of data to the European databank of medical devices (hereinafter referred to as the “Eudamed”);
- g) in a manner allowing for remote access, maintain and publish the list of providers of healthcare services establishing an ethics committee referred to by [Section 16](#);
- h) authorise the conduct of a medical device clinical investigation and issue approval of changes to the documentation of the medical device clinical investigation;
- i) decide on suspension or halting of a clinical investigation;
- j) perform
 1. the monitoring of the course of investigation into adverse incidents carried out by manufacturers and, where necessary, intervene in their investigation and adopt timely necessary measures,
 2. its own investigation into adverse incidents, where necessary; in this activity, cooperate with the European Commission (hereinafter referred to as the “Commission”), other Member States and concerned authorities of foreign countries,
 3. the monitoring of efficiency of the conduct of safety corrective actions;
- k) decide on the withdrawal of medical devices from the market or on their recall in cases of unauthorised use of the CE mark²⁾;
- l) decide on the withdrawal of medical devices from the market or on their recall for technical or health reasons, associated with the properties or efficacy of the medical device;
- m) be the control authority referred to by this act and the act governing technical requirements for products;

- n) issue free sale certificates referred to by [Section 38, paragraph 2](#);
- o) issue first-instance decisions on administrative offences in the area of medical devices and on the suspension or termination of the use of a medical device;
- p) within the scope of its powers, cooperate with the concerned authorities of foreign countries and of the Union;
- q) inform the Commission and concerned authorities of the Member States about decisions issued in compliance with [Section 39](#) together with the reasons leading to their issuance; and
- r) inform the Commission and the concerned authorities of the Member States about measures adopted or considered in order to minimise recurrence of adverse incidents, including information about such adverse incidents.

TITLE III CLINICAL EVALUATION AND PERFORMANCE EVALUATION

Chapter 1 General provision Section 10

A conformity assessment of a medical device shall always include clinical evaluation or performance evaluation, unless stipulated otherwise by this Act.

Chapter 2 Clinical Evaluation

Division 1 Course of clinical evaluation

Section 11 Basic terms

(1) Clinical evaluation shall mean a process the purpose of which is a critical evaluation of clinical data and demonstration of safety and efficacy of the medical device whilst the intended purpose determined by the manufacturer is observed in routine conditions of its use.

(2) Clinical data shall mean information on the safety or efficacy resulting from the use of the medical device.

(3) Clinical data shall be obtained by means of

- a) one or more clinical investigations of the evaluated medical device;
- b) one or more clinical investigations or other studies mentioned in literature which concern a medical device in respect of which adequacy with the evaluated medical device has been evidenced; or
- c) published or unpublished expert reports or conclusions regarding the use in clinical practice of the medical device or a properly CE-marked medical device, in respect of which adequacy with the evaluated medical device has been evidenced.

(4) Clinical investigation shall mean the use of the medical device in a trial subject in the process of systematic testing at the premises of a provider of healthcare services with the objective to

- a) evidence whether the tested medical device is suitable for use in compliance with the intended purpose, particularly in respect of safety and efficacy;
- b) establish the influence of the medical device upon the trial subject; and

c) specify the side effects of the tested medical device and evaluate whether they represent acceptable risks.

(5) A multicentric clinical investigation shall mean a clinical investigation conducted in compliance with a single clinical investigation plan at several professional workplaces by several investigators.

Section 12

Conduct of clinical evaluation

(1) A clinical evaluation shall include

- a) collection of clinical data on the evaluated medical device or medical device in respect of which adequacy with the evaluated medical device has been evidenced;
- b) selection of such clinical data which are relevant in terms of demonstrating the safety and efficacy of the evaluated medical device;
- c) evaluation of clinical data selected as referred to by letter b); and
- d) a final report from the clinical evaluation.

(2) A clinical evaluation shall be performed by an assessor who may be only a qualified professional with knowledge

- a) about the evaluated medical device and its use;
- b) from the sphere of medical device development, including clinical testing and biostatistics; and
- c) in the diagnostics and treatment in the area where the medical device is to be applied.

(3) The course of and outputs from the clinical evaluation shall be recorded in documentation. This documentation shall form part of the technical dossier of the medical device or shall be fully referenced by the technical dossier.

(4) The medical device shall be monitored by the manufacturer in relation to the clinical evaluation as well as following the placement of the device on the market. Data established within the scope of such monitoring shall be recorded in the clinical evaluation documentation. Where the manufacturer does not consider the post-marketing monitoring of the medical device necessary, the manufacturer shall provide a reasonable rationale thereof and shall specify it in the documentation.

(5) If, with a view to the special nature of interaction of the medical device with the human organism, to the intended purpose and manufacturer's statements, a clinical evaluation is not practicable, it shall not be performed. Non-performance of the clinical evaluation shall be properly justified by the manufacturer and the sufficiency of demonstration of conformity with the basic requirements shall be performed by evaluating the performance, comparative testing and preclinical evaluation.

(6) Where implantable medical devices and risk class III medical devices are concerned, the clinical evaluation shall be always, except for justified cases where it is possible to rely upon existing clinical data, performed in the form of a clinical investigation.

Division 2

Clinical investigation

Section 13

Terms

(1) A clinical investigation participant shall be

- a) the sponsor of the clinical investigation, which shall mean the person who orders the conduct of the clinical investigation from a provider of healthcare services, and who safeguards the commencement, management, organisation, control, and, where applicable, financing of the clinical investigation. The sponsor of the clinical investigation shall be established within the territory of a Member State or shall grant the power of attorney to a person established within the territory of a Member State;
- b) the investigator, which shall mean a medical professional with adequate expert and specialised qualification, appointed by the sponsor of the clinical investigation who safeguards the course of the clinical investigation conducted within a single professional workplace;
- c) where a multicentric clinical investigation is concerned, the principal investigator, which shall mean a medical professional with adequate expert and specialised qualification, appointed by the sponsor of the clinical investigation who is responsible for the coordination and course of the multicentric clinical investigation;
- d) other persons involved in the design, approval, conduct, control, documenting, and evaluation of the clinical investigation; and
- e) the trial subject which shall mean a natural person participating in the clinical investigation as the recipient of the effect of the investigational medical device or who is included in a control group. A trial subject may be only a healthy volunteer or a patient.

(2) A clinical investigation plan shall mean a document which contains detailed information on the purposes, objectives, procedures, management, and monitoring of the clinical investigation and on the method of keeping records on the course of the clinical investigation.

(3) An adverse incident shall mean any adverse medical event, unintended disease or injury to health or adverse clinical symptoms, including abnormal laboratory findings in trial subjects or other persons regardless of whether these are associated with the investigational medical device or not.

(4) A serious adverse incident shall mean an adverse event which results in

- a) death;
- b) serious deterioration of the state of health of the trial subject resulting in
 1. a life-threatening disease or injury to health,
 2. permanent damage of a physical structure or function,
 3. hospitalisation of the trial subject or extension of hospitalisation, or
 4. the necessity to conduct a medical procedure to prevent a life-threatening disease, damage to health, permanent damage to a physical structure or function; or
- c) jeopardy to the foetus, death of the foetus, a congenital anomaly or damage caused to child during delivery.

Section 14

Conditions governing the conduct of clinical investigations

(1) A clinical investigation shall be conducted by the investigator and other persons referred to by paragraph 2, letter j), in compliance with the intended purpose of the medical device and

conditions established by the manufacturer and sponsor of the clinical investigation. These persons shall be obliged to proceed in accordance with a predefined clinical investigation plan. They may deviate from the clinical investigation plan in case a critical situation which may result in a jeopardy to the health of the trial subject arises. Such deviation shall be forthwith notified to the sponsor of the clinical investigation.

(2) A clinical investigation may be commenced only if

- a) the sponsor of the clinical investigation has verified the fitness of the workplace for the conduct of the clinical investigation and the said workplace is fit for the conduct thereof;
- b) the foreseeable risks and discomfort do not prevail over the expected benefit for trial subjects, or, where applicable, for public health protection;
- c) the conditions referred to in [Section 18](#) have been met;
- d) a written approval of the conduct of the clinical investigation with focus upon ethical aspects has been obtained from the ethics committee³⁾;
- e) The Institute has authorised the conduct of the clinical investigation in cases where a medical device which is not CE-marked or a medical device which is used for a purpose other than the original one within the scope of the clinical investigation is concerned; this condition shall be considered fulfilled if no more than one year has expired since the coming legally into force of the Institute's decision on authorisation of the clinical investigation or of the day when 60 days of the delivery date of the application for clinical investigation authorisation to the Institute expired in case the Institute has not decided on the application;
- f) the sponsor of the clinical investigation has appointed the investigator and, where multicentric clinical investigations are concerned, also the principal investigator;
- g) a state-of-the-art biosafety test or another test which is necessary for the verification of the intended purpose and safety of the investigational medical device has been completed;
- h) the technical safety of the medical device has been evidenced pursuant to a legal regulation governing occupational safety and protection of health and legal regulations in the area of occupational injury prevention;
- i) the investigator, the principal investigator where a multicentric clinical investigation is concerned, has been informed about the results of the biosafety test, technical safety of the investigational medical device, as well as on potential risks associated with the conduct of the clinical investigation;
- j) medical professionals involved in the design, approval, conduct, control, documenting and evaluation of the clinical investigation have the appropriate expert and specialised qualification for the fulfilment of their tasks in the course of the clinical investigation;
- k) any contracts safeguarding proper course of the clinical investigation have been concluded in writing and signed by the involved clinical investigation participants; and
- l) the sponsor of the clinical investigation has concluded insurance covering damage, injury to health or death, the insurance coverage applying to the entire duration of the conduct of the clinical investigation including cases when it is not possible to evidence the fault of a specific person; the scope of insurance shall be adequate to the risks associated with the conducted clinical investigation.

(3) Where the trial subject is a person aged less than 18 years, the clinical investigation may be conducted only if, according to the latest medical science knowledge,

- a) the intended purpose of the investigational medical device is prevention against a serious disease, determination of diagnosis or improvement of a serious medical condition of such trial subjects; and
- b) the clinical investigation would not provide satisfactory results in trial subjects older than 18 years of age.

(4) If the trial subject is a pregnant or lactating woman, the clinical investigation may be conducted only if, according to the latest medical science knowledge,

- a) the intended purpose of the investigational medical device is prevention against a serious disease,

determination of diagnosis or improvement of a serious medical condition of pregnant or lactating women or unborn children;

b) the conduct of the clinical investigation poses only a slight risk for the unborn child or infant; and
c) there is a justified presumption that satisfactory results of the clinical investigation may be achieved only in case a pregnant or lactating woman participates therein.

(5) Where the trial subject is a person who is partially legally incapacitated, the clinical investigation may be conducted only if, according to the latest medical science knowledge,

a) the intended purpose of the investigational medical device is prevention against a serious disease, determination of diagnosis or improvement of a serious medical condition of persons with the same disease or medical handicap;

b) the clinical investigation, if conducted in subjects with another diagnosis or subjects with full legal capacity would not render satisfactory results; and

c) the conduct of the clinical investigation poses only a slight risk for the person with the given medical condition.

(6) Unless stipulated otherwise below, a trial subject must not be a person taken into pre-trial detention, prison or security detention or confined in other facilities by court ruling, or a person to whom healthcare services are provided without his/her consent.

(7) Where a clinical investigation has been initiated involving a person who at the time of testing is going to be taken into pre-trial detention, prison or security detention, such person must be excluded from the clinical investigation without any delay. This shall not apply if the termination of the clinical investigation would jeopardise the health of the trial subject. In such a case, the Prison Service of the Czech Republic shall enable the provider of healthcare services whom the sponsor of the clinical investigation has engaged to conduct the clinical investigation to complete the clinical investigation and shall provide any necessary cooperation thereto.

(8) Procedures adequate to the nature of the investigational medical device shall be employed in the conduct of the clinical investigation. Should unforeseen or increased risks for the trial subject arise, the conduct of the clinical investigation must be forthwith suspended and, if the risks cannot be eliminated, the clinical investigation must be terminated.

(9) The duration of the conduct of the clinical investigation and the frequency of observations shall be adequate to the nature of the investigational medical device, its intended purpose, declared safety, suitability and efficacy in a manner safeguarding the validity of expert conclusions, without unnecessary burden for the trial subject.

Section 15

Authorisation, suspension and halting of a clinical investigation

(1) A clinical investigation of a medical device which is not CE-marked or which is used for other than the original purpose within the scope of the clinical investigation may be conducted only if authorised by the Institute. The application for authorisation shall be filed by the sponsor of the clinical investigation electronically, via the Registry of Medical Devices. In addition to the particulars of the application set forth by the Administrative Code, the application shall also include the clinical investigation dossier referred to by [Section 21, paragraph 1, letter a\)](#), except for items 1, 2, and 6.

(2) The Institute shall authorise the conduct of the clinical investigation unless it identifies grounds for rejection of the application with a view to public health protection, jeopardy to the trial

subject's health or other public interest.

(3) The Institute shall decide on the application within the timeline of 60 days of its submission. In case the Institute fails to issue its decision within the aforementioned timeline, the conduct of the clinical investigation shall be considered authorised.

(4) Where the sponsor of the clinical investigation the conduct of which has been authorised by the Institute intends to implement changes to the conditions of the clinical investigation, the sponsor shall apply with the Institute for approval of such changes and shall submit to the Institute the proposed changes in the clinical investigation dossier and a written approval of the proposed changes by the ethics committee. The Institute shall inform the sponsor whether it agrees with the changes within the period of 30 days. Where the Institute does not provide its opinion within the aforementioned timeline, the changes shall be considered approved thereby.

(5) With a view to public health protection, jeopardy to the trial subject's health or other public interest, the Institute may temporarily suspend or halt the clinical investigation the conduct of which it has authorised. Repeal from the decision on suspension or halting of a clinical investigation shall have no suspensory effect. The Institute shall provide its decision and reasons therefor to all Member States and the Commission without unnecessary delay.

Section 16

Ethics committee

(1) An ethics committee shall mean an advisory body of the provider of healthcare services whose task is to supervise clinical investigations within the scope of the protection of trial subject rights and safety, with emphasis upon ethical aspects.

(2) An ethics committee provides a written approval with the conduct of the clinical investigation of a medical device and executes supervision over its course in terms of safety and execution of the rights of trial subjects. For this purpose it shall, in particular, evaluate the professional qualification of investigators, including the principal investigator, the fitness of selected procedures and groups of trial subjects, independently of the sponsor of the clinical investigation and the investigator.

(3) An ethics committee may be established by the provider of healthcare services who has been engaged by the sponsor to conduct the clinical investigation. On the basis of a written contract concluded with a provider of healthcare services who has not established it, the ethics committee may also act as the ethics committee for the said provider of healthcare services. The conditions for the operation of the ethics committee shall be safeguarded by the provider of healthcare services who has established it.

(4) The members of an ethics committee shall be medical professionals and other persons; the minimum number of members shall be five, of which the absolute majority shall be medical professionals. The chairperson and other members of the ethics committee shall be appointed and dismissed by the statutory body of the provider of healthcare services. The members of the ethics committee may be only natural persons who have not been sentenced for intentional crime and who provide the concerned provider of healthcare services with

- a) an extract from the Penal Register;
- b) a written consent with their membership in the ethics committee;
- c) an affidavit to the effect that they do not have any personal relationship to the subject matter of the clinical investigation which could cause a conflict of interest and should such relationship arise at

the time of their membership in the ethics committee they shall always inform the provider of healthcare services thereof; and
d) a written agreement to maintain confidentiality in respect of facts learnt in relation to their membership in the ethics committee.

(5) The meetings of the ethics committee shall be oral and non-public. The voting of the ethics committee shall be public. Each member shall have one vote. The ethics committee adopts a decision by absolute majority of votes of all members. In case of equal number of votes the chairperson's vote shall prevail.

(6) The provider of healthcare services shall notify the Institute of
a) the establishment of an ethics committee, including its membership, within 30 days of establishment of the ethics committee; and
b) the dissolution of an ethics committee without any delay.

Section 17

(1) The sponsor of the clinical investigation shall be obliged to announce in writing the intention to conduct a clinical investigation to the concerned ethics committee in writing. Together with the notification, the sponsor shall submit the clinical investigation dossier referred to by [Section 21, letter a\)](#) except for items 5 and 6. The ethics committee shall approve or decline the conduct of the clinical investigation in writing within 60 days of the delivery of the notification. This period shall not include time from the ethics committee's request for missing source materials to the date of their delivery by the sponsor.

(2) Where it is necessary to change the conditions of a clinical investigation approved by the ethics committee, the sponsor of the clinical investigation shall apply with the concerned ethics committee for a written approval of the changes to the conditions of the clinical investigation, presenting the ethics committee with the proposed changes in the clinical investigation dossier.

(3) An ethics committee shall revoke its approval with the conduct of a clinical investigation in writing, if a) new facts negatively affecting the trial subject safety arise and such facts cannot be forthwith eliminated; or b) the sponsor of the clinical investigation, the investigator or the principal investigator seriously breach their basic obligations set forth by [Sections 19](#) and [20](#).

(4) For the period of at least 15 years of the dissolution of an ethics committee established thereby, the provider of healthcare services shall keep the minutes of meetings of the ethics committees, reports and correspondence pertaining to clinical investigations, the list of ethics committee members, including the specification of their professional qualification, and any updates thereto.

(5) If the operation of an ethics committee dissolved in the course of a clinical investigation is not taken over by another ethics committee, the ethics committee's approval of the conduct of the concerned clinical investigation shall become void as of the time of dissolution of the ethics committee.

Section 18 Informed consent

(1) An informed consent with participation in a clinical investigation (hereinafter referred to as the "Informed consent") shall mean a voluntary and provable expression of the will of the person

who is to become a trial subject, or his/her guardian or custodian, to undergo the clinical investigation, confirmed by the signature of the trial subject or, where applicable, his/her guardian or custodian.

(2) The informed consent shall be granted in writing prior to the commencement of the clinical investigation, unless stipulated otherwise below. In case the informed consent is withdrawn in the course of the clinical investigation, the trial subject must be withdrawn from the clinical investigation.

(3) The person who is to become a trial subject must be adequately informed by the investigator about the conditions under which the clinical investigation is to be conducted as well as about the risks implied for the trial subject by participation in the clinical investigation as well as by potential withdrawal from the clinical investigation.

(4) Should new information relevant to the continued participation of the trial subject in the conducted clinical investigation become available, the trial subject must be informed of such facts by the investigator without any delay. An additional informed consent of such fact or, where applicable, withdrawal of the informed consent, shall be drafted.

(5) Information referred to by paragraphs 3 and 4 shall be provided in writing, clearly phrased, and in a language which the trial subject understands. The information shall form part of the informed consent and shall include

- a) information about the clinical investigation, including the definition of its objective;
- b) the anticipated duration of the clinical investigation and the anticipated time of participation of the trial subject in the clinical investigation;
- c) identification and description of the tested medical device;
- d) list of healthcare procedures to be conducted in the trial subject;
- e) information on potential benefits of the clinical investigation for the trial subject;
- f) information on foreseeable risks and potential discomfort associated with participation in the clinical investigation;
- g) information on other treatment or diagnostic options;
- h) information on the processing of obtained personal data of the trial subject, including information about safeguarding confidentiality thereof;
- i) the rights and obligations of the trial subject, including
 1. the right to withdraw from the clinical investigation at any time and the right for information about the method of withdrawal from the clinical investigation and medical risks associated with such withdrawal, and
 2. the right for the provision of compensation of damages in case of an injury to the health of the trial subject or the trial subject's death arising from his/her participation in the clinical investigation.

(6) Where practicable, the opinion of a minor without full legal capacity on his/her potential participation in the clinical investigation shall be obtained. Where adequate with regard to the intellectual and mental maturity typical for the age of such minor, an informed consent may be provided by such person. The investigator shall inform the minor's guardian of the obtained opinion or informed consent of the minor without unnecessary delay. The opinion of such person or the reason why such opinion could not be obtained shall be recorded in the medical records kept about the minor.

(7) Where the trial subject is a partially legally incapacitated person, paragraph 6 shall apply accordingly, but the age of the person shall not be taken into account and the person's custodian

shall be informed about the obtained opinion or informed consent of the person.

(8) If, with a view to his/her state of health, the trial subject is unable to grant informed consent prior to the commencement of the clinical investigation, which aims at the trial subject's direct benefit, he/she shall provide his/her written consent at the time he/she is informed about the nature, significance, impacts and risks of the clinical investigation. In such a case, the inclusion of the trial subject in the clinical investigation shall be conditioned by the execution of a record of this fact in the medical records kept about the patient, which shall be signed by the investigator and a witness.

Section 19

Obligations of the sponsor of a clinical investigation

- (1) The sponsor of a clinical investigation shall be obliged to
- a) appoint an investigator who must
 - 1. have adequate expert and specialised qualification, expertise and knowledge of the use of the investigational medical device,
 - 2. be licenced to conduct the concerned professional activity, and
 - 3. know the clinical environment where the clinical investigation is to be conducted;
 - b) safeguard the preparation of the clinical investigation dossier; and
 - c) conclude written contracts referred to in [Section 14, paragraph 2, letter k](#)).
- (2) The sponsor of a clinical investigation shall be, moreover, obliged to
- a) safeguard, following an agreement with the investigator,
 - 1. the collection and evaluation of statistical data,
 - 2. the selection of trial subjects, and
 - 3. the methods and procedures of recording and analysing any adverse incidents and serious adverse incidents arising from the testing of the medical device;
 - b) safeguard for the investigator
 - 1. the investigator's brochure, which shall men a document containing a suite of technical, clinical, and preclinical data about the investigational medical device which are relevant for the participants of the clinical investigation, and, if applicable, any other information necessary for the conduct of the particular clinical investigation,
 - 2. guidance, instructions for use, and demonstration focused upon the intended purpose of the investigational medical device,
 - 3. technical data about the investigational medical device, including risk analysis results,
 - 4. information obtained from preclinical testing related to the subject-matter of the clinical investigation,
 - 5. declaration of the manufacturer or authorised representative to the effect that the concerned medical device meets basic requirements stipulated for medical devices in conformity assessment referred to by other legal regulations governing technical requirements for products, except for aspects which form the subject-matter of the clinical investigation, and that with a view to these aspects, any preliminary precautions to protect the health and safety of trial subjects have been adopted, and
 - 6. information on whether the medical device contains any active substance, human blood or plasma derivatives, or whether it has been manufactured using non-live tissues or cells of human or animal origin or derivatives thereof;
 - c) approve and endorse with signature
 - 1. the clinical investigation plan, and
 - 2. the final report from the clinical investigation;

- d) contract insurance covering damages, injuries to health or death, effective throughout the conduct of the clinical investigation;
- e) provide the medical device intended for clinical investigations and specified by the clinical investigation plan to the investigator;
- f) notify the concerned ethics committee in advance and in writing of the intention to conduct the clinical investigation;
- g) prior to the commencement of the clinical investigation, where a medical device which is not CE-marked or which is to be used for a purpose other than the original intended purpose within the scope of the clinical investigation is concerned, submit an application for authorisation of the clinical investigation to the Institute; the obligation to submit an application for authorisation of changes to the clinical investigation in its course to the Institute shall apply accordingly;
- h) verify and in case of acceptance approve any deviation and change to the clinical investigation plan and submit proposed changes in the clinical investigation dossier to the ethics committee for approval thereby;
- i) forthwith notify the Institute and the concerned ethics committee about the commencement of the clinical investigation;
- j) in the course of the clinical investigation, provide the Institute and the concerned ethics committee with annual report on the course and evaluation of the safety of the clinical investigation, no later than by 31 January of the following year;
- k) no later than within 30 days inform the Institute and the concerned ethics committee about suspension or termination of the clinical investigation, including a rationale where early termination is concerned;
- l) following the termination of the clinical investigation, submit a report from the clinical investigation to the Institute and to the concerned ethics committee;
- m) store records on any adverse incidents and serious adverse incidents arising from the testing of the medical device notified thereto in the course of the clinical investigation for the minimum period of five years and, where implantable medical devices are concerned, for the minimum period of 15 years of the date of manufacture of the last product; and
- n) assess, together with the investigator, any serious adverse incidents arising from the testing of the medical device and inform other investigators, the Institute and the ethics committee thereabout immediately after their occurrence; the particulars of serious adverse incident reporting to the Institute are set forth by an implementing legal regulation.

Section 20

Obligations of the investigator

(1) The investigator and, where a multicentric clinical investigation is concerned, also the principal investigator shall be obliged to

- a) accept only such risks which cannot seriously jeopardise trial subjects;
- b) assess whether the state of health of the trial subjects allows for the commencement of the clinical investigation;
- c) safeguard compliance with the conditions referred to by [Section 18](#);
- d) safeguard accuracy, readability and protection of data about the clinical investigation, data in documents and case report forms; and
- e) notify, without unnecessary delay, any adverse incidents and serious adverse incidents arising from the testing of the medical device to the sponsor of the clinical investigation.

(2) The investigator and, where a multicentric clinical investigation is concerned, also the principal investigator shall be, moreover, obliged

- a) prior to the commencement of the clinical investigation to:

1. request from the sponsor of the clinical investigation any information considered necessary thereby for the conduct of the clinical investigation,
 2. acquaint himself/herself with the intended purpose of the investigational medical device and manufacturer's instructions in an appropriate extent,
 3. properly acquaint himself/herself with the clinical investigation plan, including its changes, approve the clinical investigation plan and endorse it with signature,
 4. provide a written affidavit to the effect that he/she and his/her colleagues are capable of conducting the clinical investigation and that neither he/she nor his/her colleagues have any personal relationship to the subject-matter of the clinical investigation which could cause a conflict of interest or interfere with the course of the clinical investigation, particularly with regard to concurrent conduct of another clinical investigation in which they are personally involved,
 5. provide for necessary measures covering the occurrence of adverse incidents arising from the testing of the medical device within the scope of the conducted clinical investigation,
 6. safeguard assessment of the state of health of trial subjects,
 7. provably inform trial subjects about their state of health;
- b) in the course of the clinical investigation to
1. record the participation of trial subjects in the clinical investigation,
 2. inform the trial subject's registering provider in the field of general medicine or in the field of paediatric medicine about the trial subject's participation in the clinical investigation,
 3. forthwith inform the sponsor of the clinical investigation about the occurrence of any adverse incidents and serious adverse incidents arising from the testing of the medical device and about adopted measures,
 4. discuss any necessary changes to the clinical investigation plan with the sponsor of the clinical investigation; without a written approval of the sponsor no such change may be implemented; this procedure shall not apply where a critical situation which may jeopardise the health of trial subjects arises; such deviations from the clinical investigation plan do not require prior approval of the ethics committee or of the sponsor of the clinical investigation, but must be forthwith reported to the sponsor of the clinical investigation, and
 5. check whether persons involved in the conduct of the clinical investigation properly fulfil the tasks delegated by the investigator thereto,
- c) following the termination of the clinical investigation approve and endorse with signature the final report from the clinical investigation.

Section 21

Clinical investigation dossier

- (1) The clinical investigation dossier shall comprise
- a) prior to the commencement of the clinical investigation of
 1. a written contract between the sponsor of the clinical investigation and the provider of healthcare services at whose premises the clinical investigation is to be conducted;
 2. a written contract between the sponsor of the clinical investigation and the investigator; where multicentric clinical investigation is concerned, also between the sponsor of the clinical investigation and the principal investigator; stipulating, in particular, their responsibility and confidentiality obligations,
 3. investigator's brochure,
 4. clinical investigation plan,
 5. written approval of the ethics committee,
 6. the Institute's authorisation of the conduct of the clinical investigation, if issued,
 7. an informed consent referred to by [Section 18](#),

8. a document evidencing that insurance has been contracted for the duration of the clinical investigation, covering damages, injuries to health or death,
 9. a declaration as to whether the medical device contains an active substance or a human blood or plasma derivative as its integral part,
 10. a declaration as to whether the medical device, with a view to minimising the risks of TSE infection transfer to humans, has been manufactured using tissues of animal origin, and
 11. declaration that the concerned medical device meets basic requirements set forth for medical devices in conformity assessment referred to by other legal regulations governing technical requirements for products, except for aspects which are the subject-matter of clinical investigations, and that with a view to these aspects, preliminary precautions for the protection of health and safety of the user and patient have been adopted,
- b) in the course of the clinical investigation, of records on
1. activities performed pursuant to the clinical investigation plan,
 2. previously unforeseen phenomena and measures implemented above the scope of the clinical investigation plan, and
 3. any adverse incidents and serious adverse incidents arising from the testing of the medical device, should they occur;
- c) of a report from the clinical investigation.

(2) The provider of healthcare services shall keep the clinical investigation dossier for the period of at least 15 years of the termination of the clinical investigation.

Division 3

Final report from the clinical investigation

Section 22

- (1) The final report from the clinical investigation shall contain, in particular
- a) the name of the investigational medical device and a more detailed specification thereof, including the definition of its intended purpose;
 - b) identification data of the manufacturer of the investigational medical device and the assessor for whom qualification and practical expertise shall be mentioned;
 - c) data about the assessment of the efficacy of the investigational medical device declared by the manufacturer in terms of the intended purpose;
 - d) a clearly defined mechanism of effect and the degree of effect of the investigational medical device on the patient;
 - e) assessment of safety of the investigational medical device with regard to the patient;
 - f) preclinical evaluation and chemical and physical analyses, if conducted;
 - g) a summary and conclusion which shall contain a clear position of the assessor as to whether safety and efficacy has been evidenced for the investigational medical device; and
 - h) the date and place of drafting of the final report from the clinical investigation, signature of the assessor, and signature of the manufacturer.

- (2) Where clinical data have been obtained through the procedure referred to by [Section 11, paragraph 3, letter b\) or c\)](#), the final report from the clinical investigation shall, furthermore, contain
- a) evidence of equivalence of the investigational medical device and another medical device referred to by the assessor who evaluated its clinical data obtained on the basis of
 1. one or more clinical investigations or other studies mentioned in literature, or
 2. published or unpublished expert reports or conclusions about its use in clinical practice, and
 - b) a summary of used literature.

- (3) Where clinical data have been obtained through the procedure referred to by [Section 11, paragraph 3, letter a\)](#), the final report from the clinical investigation shall, moreover, include
- a) the title of the clinical investigation;
 - b) the objectives and rationale of the conduct of the clinical investigation;
 - c) the date of commencement and termination of the clinical investigation;
 - d) identification and rationale of the selection of trial subjects;
 - e) a list of medical procedures provided to the trial subjects;
 - f) a description of the methods of measuring and a rationale of the fitness of their use;
 - g) employed statistical methods;
 - h) a detailed description of adverse incidents and serious adverse incidents arising from the testing of the medical device;
 - i) a copy of the approval of the ethics committee;
 - j) a copy of the Institute's authorisation of the conduct of the clinical investigation, if issued.

Chapter 3 Performance evaluation

Section 23 Performance evaluation conduct

(1) Performance evaluation shall mean a process the result of which is a critical evaluation of data obtained from the use of an *in vitro* diagnostic medical device in compliance with its intended purpose and verification that it achieves the performance established by the manufacturer in terms of sensitivity to the relevant analysis, sensitivity to diagnosis, analytical specificity, diagnostic fitness, accuracy, repeatability, reproducibility, minimisation of interference, and detection limit determination.

(2) The sponsor of performance evaluation shall mean a person who orders the conduct of performance evaluation from a provider of healthcare services and who safeguards the commencement, management, organisation, control, and, where applicable, the financing of performance evaluation. The sponsor of performance evaluation must be established within the territory of a Member State or must grant a power of attorney to a person established within the territory of a Member State.

(3) Performance evaluation of an *in vitro* diagnostic medical device shall be conducted pursuant to [Section 11, paragraphs 1 and 2](#) accordingly, with a view to the absence of a direct effect of the evaluated *in vitro* diagnostic medical device upon the diagnosed person.

(4) The provisions of [Section 11, paragraphs 3 and 4](#) shall be applied to performance evaluation accordingly.

Section 24 Performance evaluation notification

The performance evaluation of an *in vitro* diagnostic medical device which is not CE-marked or which is used for a purpose other than the original intended purpose within the scope of the performance evaluation, may be conducted at the premises of a provider of healthcare services established within the territory of the Czech Republic only if notified to the Institute. The notification shall be filed by the sponsor of the performance evaluation or by a person to whom the sponsor has granted a power of attorney referred to in [Section 23, paragraph 2](#), electronically via the Registry of

Medical Devices, no later than within 15 days before the commencement of the performance evaluation. The particulars of the notification are set forth by an implementing legal regulation.

Section 25

Final report from performance evaluation

The final report from performance evaluation shall contain, in particular,

- a) the name of the evaluated *in vitro* diagnostic medical device, a more detailed specification thereof and definition of its intended purpose;
- b) a list of most common diseases which may be evidenced or ruled out by means of the *in vitro* diagnostic medical device;
- c) identification data of the manufacturer of the evaluated *in vitro* diagnostic medical device and of the assessor;
- d) a list of used reference materials;
- e) a list and description of employed methods of measurement;
- f) number of tested samples;
- g) a list of clinical laboratories, where the performance evaluation has been conducted outside the premises of the manufacturer;
- h) a list of obtained specificity, sensitivity, accuracy, and reproducibility parameters;
- i) the number of trial subjects involved in the performance evaluation where medical devices for self-testing are concerned;
- j) a summary and conclusion containing a clear position of the assessor as to whether the performance of the *in vitro* diagnostic medical device has been evidenced; and
- k) the date and place of drafting of the final report from the performance evaluation, signature of the assessor, and signature of the manufacturer.

TITLE IV

REGISTRATION AND NOTIFICATION

Chapter 1

Registration of persons handling medical devices

Section 26

Notification duty

(1) A person established within the territory of the Czech Republic who intends to place medical devices on the market under its own name or business or company name must notify its operation of a manufacturer to the Institute prior to the commencement of the placing of medical devices on the market.

(2) A person established within the territory of the Czech Republic who intends to represent a manufacturer established outside the territory of the Member States, must notify its operation of an authorised representative to the Institute prior to the commencement of this operation.

(3) A person who intends to act as an importer, distributor or a servicing person within the territory of the Czech Republic, must notify its operation of an importer, distributor or a servicing person to the Institute prior to the commencement of this operation. This obligation shall not apply to importers and distributors of risk class I medical devices and *in vitro* diagnostic medical devices which are not placed on list A or list B and which are not medical devices intended for self-testing.

(4) A person established within the territory of the Czech Republic, who acts as a notified body, must notify its operation of a notified body to the Institute no later than within the period of six months of the start date of its operation.

(5) A sponsor of a clinical investigation conducted at the premises of a provider of healthcare services established within the territory of the Czech Republic must notify its activity to the Institute prior to the commencement of the clinical investigation.

(6) Another person may be authorised to file a notification of a person via the Registry of Medical Devices. The assignor may grant and the assignee may accept the power of attorney also in electronic format via the Registry of Medical Devices.

Section 27

Contact person

(1) A person handling medical devices referred to in [Section 26](#) shall appoint a contact person.

(2) The contact person must be professionally qualified for the safeguarding of communication between the person handling medical devices and state administration authorities.

Section 28

Particulars of notification

(1) The notification of a person shall be submitted electronically via the Registry of Medical Devices.

(2) In addition to the particulars set forth by the Administrative Code, the notification must include

- a) the name, telephone and address of electronic mail of the contact person;
- b) identification of the notified activity;
- c) where manufacturers of custom-made medical devices are concerned, the specification of the generic group of medical devices manufactured thereby;
- d) where authorised representatives are concerned, data about the authorised representative, including the name, business or name of the person and address of its registered office;
- e) where persons servicing medical devices are concerned, the list of manufacturers whose medical devices are serviced thereby, containing the business or person's name and address of its registered office, a copy of a certificate of specialised maintenance training as referred to by [Section 65, paragraph 4, letter b\)](#) or [Section 66, paragraph 2, letter b\)](#) from each manufacturer or its authorised person and a copy of authorisation of such person by the manufacturer;
- f) other data handed over by the Czech Republic to Eudamed on the basis of Commission decisions published in the Official Journal of the European Union.

Section 29

Procedure for registration of persons

(1) Registration of a person is completed by the issue of a certificate of compliance with the notification duty. The Institute shall enter the person in the Registry of Medical Devices without unnecessary delay, once the notification duty has been met. If any of the requirements stipulated by [Section 28](#) has not been met, the Institute shall invite the applicant to supplement the notification.

(2) Upon entry in the Registry of Medical Devices, the Institute shall assign a registration number to any registered manufacturer, authorised representative, importer, distributor, servicing person, clinical investigation sponsor and notified body. Where registration of several activities referred to by this Act has been done for a single person, only a single registration number shall be assigned thereto.

(3) In case of a change to the data specified in the registration, the manufacturer, authorised representative, importer, distributor, servicing person, clinical investigation sponsor, or notified body shall be obliged to notify the change to such data to the Institute in electronic format via the Registry of Medical Devices within the timeline of 30 days. The notification of change to data must contain the registration number assigned by the Institute and the updates of the data which have been changed. The Institute shall perform the change of registration without unnecessary delay.

(4) If the Institute identifies a duplicate record for a person, it shall decide ex officio about the deletion of the duplicate record of the person from the Registry of Medical Devices. The decision about deletion shall be the first act in the procedure and shall have no suspensory effect.

(5) Upon request of the manufacturer, authorised representative, importer, distributor, servicing person, clinical investigation sponsor, or notified body, the Institute shall perform the deletion of the person from the Registry of Medical Devices.

Section 30

Validity and extension of registration of a person

(1) Registration of a person shall be effective for the period of five years of the date of issue of the certificate of compliance with the notification duty.

(2) Registration of a person may be repeatedly extended, always for the period of five years. A person who intends to continue to carry out the notified operation, shall notify the Institute of such fact no sooner than six months before the expiry of its validity, no later, however, than two months before its expiry; [Section 28](#) shall apply accordingly to the particulars of notification. The Institute shall extend the registration without unnecessary delay.

(3) The period of extension of registration shall follow-up on the last day of the originally established validity of registration.

Chapter 2

Notification of medical devices

Section 31

Notification of medical devices placed on the market by the manufacturer or authorised representative

(1) If the manufacturer or authorised representative is established within the territory of the Czech Republic, it shall be obliged to file application for notification of a medical device placed on the market thereby to the Institute, no later than within 15 days of the date of the placement of the medical device on the market. This obligation shall apply to the authorised representative

established within the territory of the Czech Republic also in cases when the medical device is placed on the market by another person. This obligation shall not apply to custom-made medical devices.

(2) Another person may be authorised to file the application for notification of a medical device. The assignor may grant and the assignee may accept the power of attorney also in electronic format via the Registry of Medical Devices; the power of attorney may be granted in this manner only to a person authorised to submit the notification pursuant to [Section 26, paragraph 6](#).

Section 32

Particulars of the application for notification of medical devices placed on the market by the manufacturer or authorised representative

(1) The application for notification of a medical device as per [Section 31](#) shall be filed electronically via the Registry of Medical Devices.

(2) In addition to the particulars stipulated by the Administrative Code, the application must include

- a) the registration number of the manufacturer or authorised representative assigned by the Institute;
- b) the trade name of the medical device;
- c) the name supplement identifying each variant of the medical device, if it exists;
- d) the catalogue number of each variant of the medical device assigned by the manufacturer, if such number exists;
- e) the intended purpose in the Czech and English languages;
- f) the code and name of the generic group of the medical device;
- g) information that an *in vitro* diagnostic medical device belongs to list A or list B or is a medical device intended for self-testing or belongs among other *in vitro* diagnostic medical devices, or information that it concerns an active implantable medical device; in other cases the risk class;
- h) information on whether a clinical investigation has been conducted;
- i) the date of the placement of the medical device on the market;
- j) for medical devices with mandatory involvement of the notified body in the conformity assessment process the number of the certificate issued by the notified body, the number of the notified body who issued the certificate, and a copy of a valid certificate;
- k) a copy of the final report from the clinical investigation or performance evaluation;
- l) the current version of the instructions for use in the Czech language; such condition does not need to be fulfilled for risk class I or IIa medical devices, if the manufacturer has established that it is not necessary for the safe use of the medical device;
- m) effective declaration of conformity; and
- n) other data handed over by the Czech Republic to Eudamed on the basis of Commission decisions published in the Official Journal of the European Union.

Section 33

Notification of medical devices supplied by a distributor or importer

(1) The distributor or importer of a medical device shall be obliged to submit an application for notification of the medical device to the Institute no later than within 15 days of the date of its placement on the market or supply to the market in the Czech Republic. This obligation shall not be applicable to risk class I custom-made medical devices and *in vitro* diagnostic medical devices which do not belong to list A or list B and which are not medical devices intended for self-testing.

(2) Where the medical device has been already notified, any other distributor or importer of the concerned medical device shall be obliged to notify the Institute of the fact that this medical device is also distributed or imported thereby. Such notification shall be filed by the distributor or importer electronically, via the Registry of Medical Devices.

(3) Another person may be authorised to file the application for notification of a medical device. The assignor may grant and the assignee may accept the power of attorney also in electronic format via the Registry of Medical Devices; the power of attorney may be granted in this manner only to a person authorised to submit the notification pursuant to [Section 26, paragraph 6](#).

Section 34

Particulars of the application for notification of medical devices supplied by a distributor or importer

(1) The application for notification of a medical device supplied by a distributor or importer shall be filed electronically via the Registry of Medical Devices.

(2) In addition to the particulars set forth by the Administrative Code, the application must contain

- a) the registration number of the distributor or importer assigned by the Institute;
- b) the name, business name or name of the manufacturer and address of its registered office;
- c) for manufacturers established outside the territory of the Member States the name, business name or name of the authorised representative and the address of its registered office;
- d) the trade name of the medical device;
- e) the name supplement identifying each variant of the medical device, if it exists;
- f) the catalogue number of each variant of the medical device assigned by the manufacturer, if such number exists;
- g) the intended purpose in the Czech language;
- h) information that an *in vitro* diagnostic medical device belongs to list A or list B or is a medical device intended for self-testing or belongs among other *in vitro* diagnostic medical devices, or information that it concerns an active implantable medical device; in other cases the risk class;
- h) for medical devices with mandatory involvement of the notified body in the conformity assessment process the number of the certificate issued by the notified body and the number of the notified body, who issued the certificate; and
- j) the current version of the instructions for use in the Czech language; such condition does not need to be fulfilled for risk class I or IIa medical devices, if the manufacturer has established that it is not necessary for the safe use of the medical device.

Section 35

Procedure of medical device notification

(1) Notification of a medical device is completed by the coming legally into force of the decision on notification. No repeal may be filed from an Institute's decision fully granting the application of the applicant. The Institute shall enter the medical device in the Registry of Medical Devices without unnecessary delay.

(2) Where the Institute learns that the product is not a medical device or that the attachment

of the CE mark has been unauthorised, it shall decline the application. In such a case it shall be assumed that the applicant did not meet the obligation set forth by [Section 31](#) or [33](#).

(3) Upon entry in the Registry of Medical Devices, the Institute shall assign one file number to each notified medical device and an identification code to each variant of the medical device.

(4) In case of changes to the data mentioned in the notification, the manufacturer, authorised representative, distributor or importer shall be obliged to submit an application for change to the notification to the Institute in electronic format via the Registry of Medical Devices within 30 days. The application must include the registration number of the applicant, the file number of the medical device, and the identification code of each variant of the medical device, and the update of data which have been changed.

(5) Should new facts implying that the product notified as a medical device is not a medical device or that the CE mark has been attached thereto illegally become available, the Institute shall decide ex officio about its deletion from the Registry of Medical Devices. If the Institute identifies a duplicate notification of a medical device, it shall decide ex officio about the deletion of the duplicate record; the decision about such deletion shall be the first act in the procedure and shall have no suspensory effect.

(6) Upon request of the manufacturer, authorised representative, distributor or importer, the Institute shall publish information that the medical device is no longer placed on or supplied to the market by these persons in the Registry of Medical Devices.

Section 36 **Validity and extension of medical device notification**

(1) A medical device notification shall be effective for the period of five years of the date of coming legally into force of the decision on notification.

(2) The notification may be repeatedly extended, always for the period of five years. The application for notification extension may be filed six months before the expiry of its validity, no longer, however, than two months prior to its expiry; [Section 32](#) shall apply accordingly to the particulars of applications for notification extension as per [Section 31](#); [Section 34](#) shall apply accordingly to the particulars of applications for notification extension as per [Section 33](#). The Institute shall issue the decision on notification extension without unnecessary delay.

(3) The period of notification extension shall follow up on the last day of the originally established validity of the notification.

Chapter 3 **Free sale certificate**

Section 37

(1) A free sale certificate shall mean a public instrument certifying that the medical device has met the conditions for placement on the market. The free sale certificate shall be issued to the

manufacturer of a notified medical device established within the territory of the Czech Republic upon its request for the purposes of export of the medical device outside the Member States.

(2) The application shall be filed electronically via the Registry of Medical Devices and, in addition to the particulars set forth by the Administrative Code, must contain

- a) the registration number of the manufacturer;
- b) the file number of the medical device and identification codes of its variants; and
- c) information as to whether an electronic or documentary issue of the free sale certificate is required.

Section 38

(1) The Institute shall verify in the Registry of Medical Devices whether the concerned medical device has been notified and whether no change has occurred since the notification completion date which would prevent the issue of the free sale certificate.

(2) The Institute shall issue the free sale certificate to the applicant or decline the application without unnecessary delay.

(3) The free sale certificate shall be effective for the period of five years of the date of its issue, no longer, however, than for the period of validity of the notification of the medical device specified thereon. Upon request, a new free sale certificate may be issued even in case the previous free sale certificate is still effective.

TITLE V

UNAUTHORISED ATTACHMENT OF THE CE MARK AND CLASSIFICATION

Section 39

Unauthorised attachment of the EC mark

(1) If the attachment of the CE mark to a product which has been placed on the market as a medical device has been unauthorised or if this mark is missing contrary to the act governing technical requirements for products, the Institute shall invite the manufacturer of the medical device or its authorised representative to rectify the situation. If the manufacturer or authorised representative fails to rectify the situation no later than within 60 days of the delivery date of the invitation referred to in sentence one, the Institute shall issue a decision on withdrawing the product from the market. Where the product may jeopardise the health of users, the Institute shall issue a decision of withdrawal from the market and on recall without prior invitation for rectification of the situation; the Institute shall forthwith inform the manufacturer or authorised person of such procedure.

(2) Documents of the procedure referred to by paragraph 1 shall be delivered by means of a public decree, in a way allowing for remote access. The document shall be considered delivered on the fifth day of its placement on the notice board.

(3) If the Institute issues a decision on withdrawal from the market or on recall as referred to by paragraph 1, it shall inform the Commission and the concerned authorities of the Member States to this effect.

Section 40

Decision on medical device classification

(1) If, on the market in the Czech Republic, a medical device is placed, in respect of which doubts as to whether it has been correctly classified by the degree of medical risk pursuant to [Section 6, paragraph 1](#) by the manufacturer arise, the Institute shall issue a decision on classification.

(2) The procedure referred to in paragraph 1 shall be initiated by the Institute upon request or ex officio.

(3) If it not possible to issue a decision on classification pursuant to paragraph 1 on the basis of available evidence, or where a type of a medical device which is not uniformly classified in the Member States is concerned, the Institute shall submit an application to the Commission for the issuance of a decision on correct classification of the medical device and for the issuance of a measure for the entire Member State market.

Section 41

Decision on a border-line product

(1) The Institute shall issue a decision by which it shall determine whether a product is or is not a medical device, in case where

- a) such product fulfils the definition of a medical device although it has not been properly placed by the manufacture on the market as a medical device; or
- b) such product does not fulfil the definition of a medical device, although it has been placed by the manufacturer on the market as a medical device.

(2) The procedure referred to in paragraph 1 shall be commenced by the Institute upon request or ex officio.

(3) Where, with a view to available evidence, it is not possible to issue a decision or where a product which is defined as a medical device in some Member States but not in others is concerned, the Institute shall submit an application to the Commission for the issuance of a decision on proper determination of the product and for the issuance of a measure for the entire Member State market.

TITLE VI

DISTRIBUTION AND IMPORT

Chapter 1

Distribution

Section 42

(1) Distribution may be carried out only a by a distributor registered by the Institute.

(2) A distributor may supply the medical device only to another distributor, provider of healthcare services, dispensing person or seller.

Section 43

A medical device must not be distributed, if the safety or efficacy of the medical device may be compromised due to the following:

- a) the storage conditions established by the manufacturer have not been observed;
- b) it is past its expiry;
- c) its original packaging has been interfered with, or labelling is missing or is not readable; or

d) its technical condition has deteriorated.

Chapter 2 Import

Section 44

(1) Import may be carried out only by an importer registered by the Institute.

(2) A importer may supply the medical device only to a distributor, provider of healthcare services, dispensing person or seller.

Chapter 3 Joint provisions on distribution and import

Section 45

(1) Only a medical device in respect of which a declaration of conformity has been issued and which has been CE-marked may be distributed and imported. The condition set forth by sentence one shall not apply to the distribution of custom-made medical devices.

(2) The distributor and importer shall be obliged to proceed in compliance with good distribution and import practice, which shall mean a suite of rules stipulating the requirements for the maintaining of safety and performance of the medical device, particularly, to

a) safeguard the storage and handling of the medical device in compliance with instructions for use and other instructions of the manufacturer; where risk class IIb and III medical devices and active implantable medical devices are concerned, the distributor and importer must be trained by the manufacturer, authorised representative or a person appointed thereby in writing; the person who completed the training of the distributor or importer shall issue a certificate of such training for the distributor or importer; the training obligation shall not be applicable to persons who handle class IIb and III medical devices the use and handling of which is generally known; the list of such medical devices is defined by an implementing legal regulation;

b) observe the rules of good distribution and import practice defining the scope of obligations aimed at maintaining the original properties of the medical device within the scope of distribution and import;

c) regularly check the medical device and, if applicable, exclude it from further distribution with a view to potential risk of compromised safety or efficacy of the medical device;

d) provide their contractor and client with any important information which may affect the safety and health of users of the distributed medical device of which they have learnt; and

e) store any documents related to the distributed or imported medical device for the period of five years;

more detailed rules of good distribution and import practice are stipulated by an implementing legal regulation.

**TITLE VII
PRESCRIBING, DISPENSING, AND SALE**

**Chapter 1
Prescribing
Section 46
Medical prescription**

(1) A medical device may be prescribed only by a medical doctor or a dentist (hereinafter referred to as the “doctor”), by means of issuing a medical prescription which shall be an order.

(2) A medical device which, even if its intended purpose is observed, may jeopardise the health or life of humans if not used under medical supervision, may be issued upon order only. The list of groups of such medical devices is set forth by an implementing legal regulation.

(3) A medical device shall be issued on order also in case the patient is entitled to its reimbursement pursuant to the act governing public health insurance.

**Section 47
Order issuance**

(1) An order may be issued in documentary form only.

(2) An order may not bear symbols or elements which restrict the readability of the completed data, data about other providers of healthcare services, or any advertising statements.

(3) If the prescribing doctor prescribes a medical device which, pursuant to the act governing public health insurance, is not reimbursed from public health insurance, or is partially reimbursed therefrom, he/she shall be obliged to notify the patient of such fact.

(4) Upon request for repeated prescription of a medical device, the prescribing doctor shall assess, where practicable, the condition of the used medical device. If the medical device is satisfactory in terms of its therapeutic, performance, and safety aspects, the doctor shall not prescribe a new medical device of the same type.

**Section 48
Handling of the order and its expiry**

(1) No uncompleted orders form may be stamped with the stamp of the provider of healthcare services.

(2) An order with a prescribed medical device may be used within 90 days of the date of its issue, unless specified otherwise by the doctor with a view to the patient’s state of health or the nature of the medical device.

(3) The particulars of the order are stipulated by an implementing legal regulation.

Chapter 2

Dispensing

Section 49 Conditions of dispensing

(1) Only a medical device in respect of which a declaration of conformity has been issued and which has been CE-marked may be dispensed; this condition shall not be applicable to custom-made medical devices.

(2) A medical device may be dispensed only in a pharmacy, medical device dispensary, optician's shop, or at the premises of a contracted dispensing person.

(3) In a pharmacy or medical device dispensary, a medical device may be dispensed only by

- a) a pharmacist with specialised qualification;
- b) a pharmacist with expert qualification;
- c) a pharmaceutical assistant, assistant with specialised qualification for the expert workplace for medical device dispensing;
- d) a pharmaceutical assistant with expert qualification; or
- e) orthotist-prosthetist qualified for the performance of a profession without expert supervision, where orthotic-prosthetic medical devices are concerned.

(4) An optical medical device may be dispensed only in an optician's shop. Such medical device may be dispensed only by

- a) an optometrist;
- b) an eye optician with diploma or eye technician with a diploma; or
- c) an eye optician or eye technician.

Section 50 Dispensing by mail

(1) Dispensing by mail shall mean the dispensing of a medical device on order by mail.

(2) Dispensing by mail may be safeguarded solely by the dispensing person.

(3) Dispensing by mail shall be forbidden for medical devices referred to by [Section 46, paragraph 2](#).

Section 51 Obligations of persons safeguarding dispensing by mail

In the dispensing of a medical device by mail the dispensing person shall be obliged to safeguard

- a) the publication of information about dispensing by mail, the offer of medical devices, their price, and costs associated with the mail dispensing on its website;
- b) the packaging and transportation of consignments containing medical devices to be delivered to the ordering party in a manner which will ensure that their quality is maintained; the person safeguarding mail dispensing shall be responsible for the maintaining of the quality of the medical devices, even in case such person contracts the transportation of medical devices with another person;
- c) that the deliveries are sent to the ordering party no later than within two working days of the date

of receipt of the purchase order or that the ordering party is informed about a longer delivery period before the latter places a binding purchase order for such medical device;

d) an information service provided pursuant to [Section 49, paragraphs 3 and 4](#) throughout predefined operating hours; such information service shall, moreover, serve for the purposes of collection and hand-over of information about adverse incident occurrence;

e) the possibility to return medical devices under complaint in a manner which will not incur any costs to the ordering party; such medical devices shall become non-usable and their removal must be safeguarded.

Section 52 Replacement

(1) During the dispensing of a medical device prescribed on order, the dispensing individual shall inform the patient about possible alternatives of the prescribed medical device and with the consent of the latter shall be authorised to replace it with another medical device which is replaceable with the prescribed medical device in terms of efficacy and intended purpose. The performed replacement shall be identified by the dispensing individual on the order form.

(2) If, with a view to the patient's state of health, the prescribing doctor or a review doctor of a health insurance company insists upon the dispensing of the prescribed medical device, he/she shall place the "Do not replace" remark on the order form. In such a case the dispensing individual may dispense only the prescribed medical device.

Section 53 Order excerpt

If the dispensing individual does not have the prescribed quantity or type of the medical device, he/she shall issue an order excerpt for the remaining medical device, which shall bear the word "Excerpt". An order excerpt shall contain data from the original order and information about the extent of the previously completed dispensing. The original order shall be supplemented with the remark "Excerpt executed" and information on the extent of the performed dispensing. [Section 48, paragraph 2](#) shall apply accordingly to the determination of the expiry of an order excerpt.

Section 54 Obligations of the dispensing person

The dispensing person shall be obliged to

a) safeguard the storage and handling of the medical device in compliance with the instructions for use and other instructions of the manufacturer;

b) regularly check the medical device and remove it with a view to potential risk of compromised safety or efficacy of the medical device;

c) provide the patient with any and all information about facts which may affect his/her safety and health in relation to the use of the dispensed medical device;

d) keep any and all documents associated with the dispensed medical device, including medical prescriptions, for the period of five years; and

e) accordingly observe other rules referred to by [Section 45, paragraph 2](#).

Section 55

Ban on dispensing

(1) A medical device must not be dispensed if its safety or efficacy has been compromised due to the following:

- a) the storage conditions established by the manufacturer have been breached;
- b) it is past its expiry;
- c) its original packaging has been interfered with or the labelling is missing or not readable; or
- d) the technical condition of the device has deteriorated.

(2) Medical devices which have been excluded from dispensing must be stored separately from medical devices which may be dispensed; these medical devices shall be handled in compliance with another legal regulation governing waste management.

Chapter 3 Sale

Section 56 Conditions of sale

(1) Only a medical device in respect of which a declaration of conformity has been issued and which has been CE-marked may be sold; this condition shall not be applicable to custom-made medical devices.

(2) The seller shall be obliged to

- a) safeguard the storage and handling of a medical device in compliance with instructions for use and other instructions of the manufacturer; in respect of risk class IIb and III medical devices and active implantable medical devices, the seller must be trained by the manufacturer, authorised representative, a person appointed in writing thereby, distributor or importer; the person who performed the training of the seller shall issue a document evidencing the completion of such training to the seller; the training obligation shall not be applicable to persons who handle class IIb and III medical devices, the use and handling of which is generally known; the list of such medical devices is stipulated by an implementing legal regulation;
- b) regularly check the medical device and remove it with a view to potential risk of compromised safety or efficacy of the medical device;
- c) provide its supplier and user with any important information which may affect the safety and health of the user of the sold medical device of which the seller has learnt;
- d) keep any documents associated with the sold medical device for the period of five years; and
- e) accordingly observe other rules set forth by [Section 45, paragraph 2](#).

Section 57

(1) A medical device must not be sold, if its safety or efficacy has been compromised due to the following:

- a) the storage conditions established by the manufacturer have been breached;
- b) it is past its expiry;
- c) its original packaging has been interfered with or the labelling is missing or not readable; or
- d) the technical condition of the device has deteriorated

(2) Medical devices which have been excluded from sale must be stored separately from medical devices which may be sold; these medical devices shall be handled pursuant to another legal

regulation governing waste management.

TITLE VIII USAGE

Section 58 General provisions

Only a medical device in respect of which a declaration of conformity has been issued and which has been CE-marked may be used in the provision of healthcare services; this condition shall not be applicable to custom-made medical devices or medical devices for which it is stipulated by this Act.

Section 59 Obligations of providers of healthcare services in the use of medical devices

(1) A provider of healthcare services shall be obliged to safeguard that

- a) the medical device is used solely for the intended purpose in compliance with the manufacturer's instructions;
- b) the medical device with a measuring function is operated in compliance with the requirements set forth by another legal regulation governing the sphere of metrology;
- c) the medical device is used in the provision of healthcare services solely by a person who, with a view to adequate education and practical expertise provides a sufficient guarantee of professional use of the medical device in compliance with its instructions for use;
- d) the person providing healthcare services by means of the medical device and the patient are advised of the necessity to make sure, prior to each use of the medical device, that it is in a proper technical condition, functional, and may be safely used, where such check of the medical device is applicable; this requirement shall accordingly apply also to the accessories, software and another product which is expected to interact with the concerned medical device;
- e) rules set forth by [Section 45, paragraph 2](#) are adequately applied in the handling of the medical device; and
- f) the medical device is serviced in compliance with this Act.

(2) The provider of healthcare services must not use the medical device in the provision of healthcare services, if

- a) it may be reasonably suspected that the safety and health of patients or third parties are jeopardised, even in case the medical device has been properly installed, or implanted in the human body, where applicable, maintained and used in compliance with its intended purpose;
- b) it is past its expiry;
- c) it exhibits shortcomings in terms of its manufacture, which may result in jeopardy to the health of patients or third parties;
- d) the safety of the medical device may be jeopardised or its efficacy compromised due to an apparently disrupted integrity of the original packaging; or
- e) instructions for use in the Czech language are not available thereto; this condition does not need to be fulfilled for risk class I or IIa medical devices for which the manufacturer has established that it is not necessary for the safe use of the medical device.

(3) If an active implantable medical device or a risk class IIb or III medical device is used in the provision of healthcare services, a record thereof must be made in the patient's medical documentation.

(4) The provider of healthcare services shall be obliged to keep records of used medical devices

- a) for which a demonstration must be made;
- b) which must be professionally serviced according to the manufacturer's instructions; and
- c) which are classified as working meters by a legal regulation governing the sphere of metrology.

The particulars of documentation of used medical devices are set forth by an implementing legal regulation.

Section 60 Information for users

(1) The provider of healthcare services shall be obliged to safeguard that instructions for use of the medical device in the Czech language and information relevant to its safe use be available to the user; the obligation to safeguard availability of instructions for use shall not apply to risk class I or IIa medical devices in respect of which the manufacturer has established that it is not necessary for the safe use of the medical device.

(2) A doctor responsible for the implantation of an implantable medical device shall be obliged to provide the patient in whom the medical device has been implanted or the patient's guardian or custodian, where applicable, with detailed information allowing for the identification of the medical device, including its accessories, together with guidance relevant to the safety of the patient and his/her conduct, including information on when the patient is to seek medical assistance, what external influences the patient is to avoid completely or which are acceptable only if suitable preventative measures are observed. A written protocol of the patient's advice signed by both parties involved must be drafted. Where the patient refuses to sign the protocol, such fact must be mentioned in the protocol and the protocol must be signed by the responsible doctor and a witness.

(2) When informing patients in relation to the use of the medical device it is necessary to observe the relevant guidance provided in the instructions for use and other information referred to by paragraph 1.

Section 61 Demonstration

(1) An active implantable medical device, a risk class IIb or III active medical device and a medical device in respect of which the manufacturer has established so may be operated only by a person who

- a) had a demonstration of the concerned medical device or a medical device of identical type conducted in compliance with the relevant instructions for use; and
- b) has been familiarised with the risks associated with the use of the concerned medical device.

(2) A demonstration may be conducted only by a person who, with a view to adequate education, practical expertise and guidance from the manufacturer provides a sufficient guarantee of professional conduct of the demonstration of the proper use of the concerned medical device.

(3) The provider of healthcare services shall be obliged to maintain and store information about any and all conducted demonstrations. The provider of healthcare services shall be obliged to store this information for the period of one year of decommissioning of the medical device.

Special use

Section 62

(1) Should the life or health of a patient be jeopardised, the doctor providing medical services may use a medical device in an off-label manner, if no other medical device of the necessary characteristics is available thereto, but under the condition that such method of use has been clinically verified in a similar type of a medical device.

(2) If the doctor intends to use a medical device in a manner referred to by paragraph 1, he/she shall inform the patient or his/her guardian or custodian, if applicable, of such fact and of potential consequences and risks of such procedure and shall make a record thereof in the patient's medical documentation. Where, due to the patient's state of health or absence of the guardian or custodian the provision of information referred to in sentence one is not practicable, the doctor shall provide the information as soon as the patient's state of health or the presence of the patient's guardian or custodian allows him/her to do so.

(3) The doctor shall make a record of the procedure referred to in paragraph 1, of the reasons for applying such procedure, and of the provision of information referred to in paragraph 2 in the patient's medical documentation.

Section 63

(1) In case of declaration of war or a state of emergency⁴⁾ and in case of provision of healthcare services using medical devices to soldiers sent outside the territory of the Czech Republic⁵⁾ the Ministry of Defence may deviate from this Act in safeguarding medical devices for the Armed Forces of the⁶⁾ Czech Republic.

(2) The Czech Republic shall be responsible of damages arising from the use of medical devices referred to by paragraph 1.

TITLE IX SERVICING AND REVISIONS

Chapter 1 Servicing

Section 64 General provision

(1) Servicing shall mean the performance of professional maintenance and repairs of a medical device in compliance with the instructions of the manufacturer, this Act and other legal regulations; repairs and professional maintenance of a custom-made medical device shall not be considered servicing referred to by this Act.

(2) A medical device may be serviced solely by a legal person or natural person-entrepreneur registered by the Institute as a servicing person.

(3) Where a medical device with a measuring function is concerned, it must be serviced in compliance with another legal regulation governing the area of metrology.

Section 65

Professional maintenance

(1) Professional maintenance shall mean the conduct of regular safety technical controls and other activities aimed at the maintaining of safety and full performance of the medical device.

(2) Professional maintenance shall, moreover, include the conduct of electrical controls of a medical device which is electrical equipment.

(3) Professional maintenance of a medical device shall be conducted with a view to its inclusion in a risk class, in the scope and frequency determined by the manufacturer. Where the manufacturer does not determine the frequency of professional maintenance of a medical device which is connected to a source of electrical energy, professional maintenance shall be conducted at least every other year.

(4) A servicing person shall be obliged to

a) ensure that professional maintenance is conducted solely by healthcare professionals with at least one year of professional practical experience and with expert qualification for the conduct of the profession of a biomedical technician, biotechnical assistant, biomedical engineer, clinical technician, clinical engineer, orthotist-prosthetist, or employees with at least three years of professional practical experience in the sphere of professional maintenance of medical devices, or employees of the servicing person, with at least three months of professional practical experience with the servicing person;

b) ensure that all employees conducting professional maintenance are trained by the manufacturer or a person authorised by the manufacturer;

c) ensure, where professional maintenance of a medical device which is an electrical equipment is concerned, that in addition to the requirements set forth by letter a) the employees conducting such professional maintenance also

1. fulfilled the requirements for employees for independent activity set forth by another legal regulation governing expert qualification in the field of electrotechnics, or

2. fulfilled the requirements for employees knowledgeable pursuant to another legal regulation governing expert qualification in electrotechnics under supervision of a person referred to by item 1; and

d) safeguard adequate material and technical equipment for the conduct of professional maintenance.

(5) The provider of healthcare services shall be obliged to keep and store records on the completed professional maintenance for the period of one year of the date of decommissioning of the medical device.

(6) The requirements governing employees conducting professional maintenance shall not apply to professional maintenance of risk class I medical devices without measuring functions or to risk class I medical devices which are not electrical equipment.

Section 66

Repair

(1) Repair shall mean a suite of actions through which a damaged medical device is brought back to original or operable condition, without changing its technical parameters or intended purpose.

- (2) A servicing person shall be obliged to
- a) ensure that the repair is conducted solely by healthcare professionals with at least a one-year professional practical experience and expert qualification for the conduct of the profession of a biomedical technician, biomedical engineer, clinical technician, clinical engineer, orthotist-prosthetist, or employees with at least three years of professional practical experience in the sphere of repairs of the concerned medical device or medical device of a similar type, or employees of the servicing person with at least three months of professional practical experience with the concerned medical device or a medical device of a similar type;
 - b) ensure that any employees conducting repairs are trained in the field of repairs of the concerned medical device within the scope established by the manufacturer; such training shall be conducted by the manufacturer or a person authorised by the manufacturer;
 - c) ensure, where repair of a medical device which is electrical equipment is concerned, that in addition to the requirements set forth by letter a) the employees conducting such repair also
 - 1. fulfilled the requirements for employees for independent activity set forth by another legal regulation governing expert qualification in the field of electrotechnics, or
 - 2. fulfilled the requirements for employees knowledgeable pursuant to another legal regulation governing expert qualification in electrotechnics under supervision of a person referred to by item 1;
 - d) ensure, where repair of a medical device which contains pressure equipment is concerned, that the repair of the pressure equipment is conducted by employees who fulfil the requirements governing expert qualification for repairs of pressure equipment set forth by another legal regulation;
 - e) ensure, where repair of a medical device which contains gas equipment is concerned, that the repair of the gas equipment is conducted by employees who fulfil the requirements governing expert qualification for repairs of gas equipment set forth by another legal regulation; and
 - f) safeguard adequate material and technical equipment for the conduct of repairs.

(3) Following the completion of a repair which could affect the construction or performance characteristics of the medical device the servicing person must ensure that the employee conducting the repair tested the safety and performance of the medical device and drafted a written protocol of such testing. The provider of healthcare services shall be obliged to store this protocol for at least one year of the decommissioning of the medical device.

(4) The requirements governing employees conducting repairs shall not be applicable to repairs of risk class I medical devices without a measuring function or risk class I medical devices which are not electrical equipment.

Chapter 2 Revision

Section 67 General provision

(1) In addition to servicing, medical devices which are connected to a source of electrical energy and medical devices which include pressure or gas equipment shall be subjected also to revisions conducted pursuant to other legal regulations. A revision shall mean an electrical revision, pressure revision, and gas revision.

(2) An electrical revision shall mean a specialised control consisting of a suite of visual controls and electrical measurements of the medical device which is firmly connected to a source of electrical energy.

(3) A pressure revision shall mean a specialised control consisting of a suite of visual controls and measurements of a medical device which includes pressure equipment.

(4) A gas revision shall mean a specialised control consisting of a suite of visual controls and measurements of a medical device which includes gas equipment.

Section 68 **Conditions governing the conduct of revisions**

(1) A revision of a medical device shall be conducted within the scope and frequency stipulated by other legal regulations governing electrical, pressure and gas revision, or by the manufacturer.

(2) The person conducting a revision shall be obliged to ensure that an electrical revision is carried out solely by employees who fulfil the requirements for expert qualification for the conduct of electrical equipment revisions set forth by another legal regulation governing expert qualification in electrotechnics.

(3) The person conducting a revision of a medical device which includes pressure equipment shall be obliged to ensure that the pressure equipment revision is conducted by employees who fulfil the requirements for expert qualification for the conduct of pressure equipment revisions set forth by another legal regulation governing pressure revisions.

(4) The person conducting a revision of a medical device which includes gas equipment shall be obliged to ensure that the gas equipment revision is conducted by employees who fulfil the requirements for expert qualification for the conduct of gas equipment revisions set forth by another legal regulation governing gas revisions.

TITLE X **VIGILANCE SYSTEM**

Section 69 **General provision**

(1) A vigilance system shall mean a system of reporting and evaluation of adverse incidents and safety corrective actions regarding medical devices.

(2) An adverse incident shall mean

- a) any failure or deterioration of characteristics or efficacy of a medical device or inaccuracy in the labelling of the medical device or in the instructions for use which resulted or could result in the death of the user or another natural person or in a serious deterioration of the state of their health;
- b) a technical or medical reason which is associated with the characteristics or efficacy of the medical device and results in the manufacturer's systematic withdrawal of the medical device from the market for reasons mentioned under letter a).

(3) A field safety corrective action shall mean an action determined by the manufacturer with the aim to reduce the risk of death or serious deterioration of the state of health in association with the use of the medical device which has been already placed on the market.

(4) A safety alert shall mean a communication intended for distributors, importers, users, or patients which is sent by the manufacturer or the authorised representative as information about

adopted field safety corrective action.

Section 70

Adverse incident and suspected adverse incident reporting

(1) The manufacturer or authorised representative shall be obliged to report in writing an adverse incident associated with its medical device to the Institute without any delay, no later than within 15 days of identification of such incident.

(2) The importer, distributor, provider of healthcare services, servicing person, dispensing person and seller shall be obliged to report in writing suspected adverse incidents arising in association with the use of a medical device in the provision of healthcare services to the manufacturer or authorised representative and to the Institute without any delay, no later than within 15 days of identification of such incident.

(3) The report referred to in paragraphs 1 and 2 shall contain

- a) data about the reporter set forth by the Administrative Code;
- b) identification data of the medical device;
- c) the name, business name of the manufacturer and the address of its registered office, if known to the reporter;
- d) the description of the adverse incident and the place and date of its occurrence;
- e) the consequences of the adverse incident; and
- f) a description of adopted actions upon the occurrence of the adverse incident or a notice that no actions have been adopted.

(4) If a report of a suspected adverse incident which presumably arose in relation to the use of a medical device in the provision of healthcare services is delivered to the Institute or the Institute identifies the concerned information from its official operation, it shall report these facts to the manufacturer or authorised representative without unnecessary delay.

Section 71

Investigation of adverse incidents

(1) In case the manufacturer learns about a suspected adverse incident, it shall forthwith initiate investigation thereof and it shall inform the Institute of this fact.

(2) The Institute shall monitor the course of adverse incident investigation by the manufacturer, and shall evaluate any preventive and corrective actions adopted or considered by the manufacturer. Where necessary, the Institute shall perform its own investigation; within the scope of such investigation, the Institute shall be authorised to inspect the concerned medical devices and related documentation at persons' handling these medical devices.

(3) The manufacturer or authorised representative shall be obliged to send to the Institute a final report about the outcomes of adverse incident investigation. The final report on the outcomes of adverse incident investigation shall include:

- a) identification data of the medical device;
- b) the name, business name of the manufacturer and address of its registered office;
- c) outcomes of the investigation; and
- d) information about adopted and considered measures.

(4) As soon as the final report on the outcomes of adverse incident investigation is delivered to the Institute, the Institute shall review the report with a view to ensuring the safety and health of users, patients and other natural persons. If the Institute finds the safety corrective action adopted by the manufacturer to be inadequate, it shall, following consultation with the manufacturer, inform the Ministry which shall adopt measures necessary for the safeguarding of safety and health of users, patients and other natural persons and for the minimisation of recurrence of the adverse incident.

(5) Without unnecessary delay, the Institute shall be obliged to inform the Commission and the concerned authorities of the Member States about measures adopted or considered by the manufacturer, Institute or Ministry aimed at the minimisation of recurrence of the adverse incidents, including information about these adverse incidents. Information for users sent by the manufacturer, authorised representative, or distributor in relation to measures aimed at the minimisation of recurrence of adverse incidents shall be published by the Institute via the Registry of Medical Devices.

(6) Reporting of adverse incidents and suspected adverse incidents referred to in [Section 70, paragraphs 1 and 2](#), information about their investigation pursuant to paragraph 1, and reporting of outcomes of investigation pursuant to paragraph 3 shall be filed by means of a form. The forms referred to in sentence one, the method of their sending to the Institute, the required scope of information about investigation and evaluation of adverse incidents and suspected adverse incidents are set forth by an implementing legal regulation.

Section 72

Adverse incident record keeping

(1) A provider of healthcare services at whose premises an adverse incident resulting in an injury to the patient's health or in the death of the patient occurred, shall be obliged to record this fact in the patient's medical documentation.

(2) The Institute shall record any adverse incidents, maintain and store documentation of their investigation for the period of 15 years; where an adverse incident associated with an injury to health or death of the user, patient or another natural person is concerned, the Institute shall store the documentation for the period of 30 years.

Section 73

Obligations of providers of healthcare services

The provider of healthcare services at whose premises a suspected adverse incident of a medical device has occurred shall be obliged to

- a) adopt any necessary measures aimed at minimising the negative consequences of the arising incident and inform the manufacturer or authorised representative and the Institute thereof;
- b) provide the manufacturer and the Institute with access to the medical device in respect of which the suspected adverse incident occurred, including any documentation for the purposes of inspection and identification of causes of the arising incident; and
- c) provide the manufacturer and the Institute with any necessary cooperation and information for the purposes of identifying the causes of the arising incident.

Section 74

Field safety corrective action

(1) Where an adverse incident occurs, the manufacturer shall be obliged to assess the risks with a view to the safety and health of users, patients and other natural persons, and, if necessary, determine a field safety corrective action.

(2) A manufacturer or authorised representative established within the territory of the Czech Republic shall be obliged to report to the Institute the determination of a field safety corrective action, including the sending of a safety alert in the Czech and English languages and inform the concerned authorities of states where the medical device has been supplied to the market about the determined field safety corrective action.

(3) The manufacturer shall be obliged to safeguard the implementation of the field safety corrective action.

(4) The manufacturer shall be obliged to inform the Institute of the completion of the determined field safety corrective action, including information about its effect, no later than within 10 days of the date of its completion.

(5) The report referred to by paragraph 2 shall be filed by means of a form. The form referred to by sentence one, the method of its sending to the Institute and essential requirements for the determination of field safety corrective actions and safety alerts are set forth by an implementing legal regulation.

Section 75

Obligations of importers, distributors and servicing persons

The importer, distributor and servicing person shall be obliged to

- a) implement the field safety corrective action determined by the manufacturer or the Institute;
- b) send to the Institute information about determined field safety corrective action and safety alert in the Czech language, no later than within 10 days of the date on which it was obtained thereby;
- c) inform the Institute of the completion of the determined field safety corrective action, no later than within 10 days of its completion.

TITLE XI

REMOVAL

Section 76

(1) With regard to the protection of life and health of humans or animals and environmental protection, the person handling medical devices shall be obliged to remove any medical device the safety or efficacy of which may be compromised due to the following:

- a) breach of storage conditions;
- b) expiry of its use-by date;
- c) interference with its original packaging or, where applicable, the absence or unreadability of the labelling, prior to the delivery to the user; or
- d) deterioration of its technical condition.

(2) In the removal of the medical device the procedure set forth by another legal regulation governing waste management and manufacturer's instructions shall be followed.

TITLE XII

MEDICAL DEVICE NATIONAL INFORMATION SYSTEM AND REGISTRY OF MEDICAL DEVICES

Section 77

Medical device national information system

(1) The Medical Device National Information System shall mean a uniform nationwide

information system of the public administration intended for

- a) the provision of information to users, patients, and providers of healthcare services in order to facilitate the correct selection of a proper medical device, safe use, proper handling of the medical device and its servicing;
- b) the support of tenders for the procurement of medical devices;
- c) the provision of information about field safety corrective actions and safety alerts;
- d) retrieval of necessary data for statistical purposes within the scope stipulated by other legal regulations, including the provision of information for international institutions;
- e) the provision of information for the purposes of science and research in the area of medical devices;
- f) the support of compliance with the obligations of the Czech Republic pertaining to the hand-over of data to Eudamed.

(2) The administrator of the Medical Device National Information System shall be the Institute.

(3) The content of the Medical Device National Information System shall be

- a) publicly accessible on the website of the Institute within the scope of data about medical devices, except for data which are subject to protection pursuant to other legal regulations;
- b) accessible to authorised employees of the Ministry for the purposes of execution of state administration in the area of medical devices;
- c) accessible to authorised employees of the Institute for the purposes of execution of state administration in the area of medical devices;
- d) accessible to authorised employees of the Czech Office for Standards, Metrology and Testing, but only in the scope of data provided by notified bodies established in the Czech Republic; and
- e) accessible to authorised employees of health insurance companies, within the scope of data necessary to safeguard the fulfilment of their obligations implied by legal regulations governing the area of public health insurance.

(4) Data shall be handed over to the Medical Device National Information System from the Registry of Medical Devices and from the administrative activities of the Ministry and the Institute.

(5) The Medical Device National Information System and the Registry of Medical Devices shall be mutually interconnected and data maintained therein may be clustered.

(6) Access rights to data maintained in the Medical Device National Information System shall be provided to entities referred to in paragraph 3, letters b) to e) by the Institute upon request of the former.

Registry of Medical Devices Section 78

(1) The Registry of Medical Devices shall mean a public administration information system intended for the collection of data about

- a) medical devices placed on the market in the Czech Republic;
- b) persons registered pursuant to this Act;
- c) adverse incidents and field safety corrective actions;
- d) conducted clinical investigations of medical devices;
- e) conducted performance evaluations of medical devices; and

f) certificates issued by notified bodies established in the Czech Republic;

(2) The administrator of the Registry of Medical Devices shall be the Ministry who may authorise the Institute to perform the administration of the Registry of Medical Devices.

(3) Data in the Registry of Medical Devices shall be administered for the purposes of

a) compliance with the obligations of the Czech Republic pertaining to hand-over of data to Eudamed;

b) provision of information to the public;

c) provision of information about adopted field safety corrective actions.

(4) Within the scope of the Registry of Medical Devices, medical devices shall be classified into several levels. The structure of the classification of medical devices is stipulated by an implementing legal regulation.

Section 79

(1) The Registry of Medical Devices shall be

a) publicly accessible on websites within the scope of data about medical devices, except for data subjected to protection pursuant to other legal regulations;

b) accessible to persons fulfilling their obligations via the Registry of Medical Devices and persons representing them on the basis of a power of attorney, within the scope of data about their person and the scope of data about medical devices notified thereby;

c) accessible to authorised employees of the Ministry for the purposes of execution of state administration in the area of medical devices;

d) accessible to authorised employees of the Institute for the purposes of execution of state administration in the area of medical devices;

e) accessible to authorised employees of the Czech Office for Standards, Metrology and Testing, but only in the scope of data provided by notified bodies established in the Czech Republic; and

f) accessible to authorised employees of health insurance companies, but only within the scope of data necessary to safeguard the fulfilment of their obligations implied by legal regulations governing the area of public health insurance.

(2) A notified body established within the territory of the Czech Republic shall be obliged to enter information about certificates issued, changed, amended, suspended and revoked thereby as well as about its refusals to issue a certificate in the Registry of Medical Devices.

(3) Anyone obliged or authorised to provide data to the Registry of Medical Devices pursuant to this Act shall have access to the data within the scope in which the data have been provided thereby.

(4) Data maintained in the Registry of Medical Devices which are subjected to protection pursuant to the act governing personal data protection and the act governing free access to information shall be non-public; other data shall be published via the Registry of Medical Devices.

(5) Access rights to data maintained in the Registry of Medical Devices shall be safeguarded for entities referred to under paragraph 1, letters b) to f) by the Institute upon request of the former.

TITLE XIII CONTROL

Section 80

(1) Control over compliance with the obligations set forth by this Act on the part of persons handling medical devices shall be executed by the Institute pursuant to the Control Code.

(2) A control of whether medical devices are placed and supplied on the market in the Czech Republic or put into service in compliance with technical requirements shall be conducted by the

Institute pursuant to the act governing technical requirements for products and the Control Code.

(3) An authorisation for control shall have the form of an identity card.

(4) The Institute may decide on the suspension or termination of the use of a medical device if the use of such device implies or in relation therewith there is an immediate jeopardy of an injury to the health of natural persons. Repeal from this decision shall have no suspensory effect. The costs associated with the fulfilment of the decision shall be borne by the provider of healthcare services.

TITLE XIV ADMINISTRATIVE OFFENCES

Section 81

Administrative offences of legal persons and natural persons-entrepreneurs in the area of clinical investigations and performance evaluations

(1) A sponsor of a clinical investigation shall commit an administrative offence by initiating a clinical investigation contrary to [Section 15, paragraph 1](#) or by implementing changes to the conditions of the clinical investigation contrary to [Section 15, paragraph 4](#).

(2) A provider of healthcare services shall commit an administrative offence by conducting a clinical investigation for a person who does not meet the conditions set forth by [Section 13, paragraph 1, letter a](#)).

(3) A provider of healthcare services shall commit an administrative offence by conducting a clinical investigation contrary to [Section 15, paragraph 1](#).

(4) A sponsor of a clinical investigation shall commit an administrative offence by failing to fulfil any of the obligations set forth by [Section 19](#).

(5) A natural person-entrepreneur as the investigator or principal investigator shall commit an administrative offence by failing to fulfil any of the obligations set forth by [Section 20](#).

(6) A sponsor of a performance evaluation shall commit an administrative offence by failing to fulfil the obligation set forth by [Section 24](#).

(7) An administrative offence shall be penalised by a fine of up to
a) 2 000 000 CZK, where an administrative offence referred to by paragraphs 1 to 4 is concerned;
b) 500 000 CZK, where an administrative offence referred to by paragraphs 5 and 6 is concerned.

Section 82

Offence in the field of clinical investigations

(1) A natural person as the investigator or principal investigator shall commit an offence by failing to fulfil any of the obligations referred to by [Section 20](#).

(2) An offence referred to by paragraph 1 may be penalised by a fine of up to 500 000 CZK.

Section 83

Administrative offences of legal persons and natural persons-entrepreneurs in the fulfilment of notification duties

(1) A manufacturer or authorised representative established in the Czech Republic, an importer, distributor, servicing person or sponsor of a clinical investigation operating within the territory of the Czech Republic shall commit an administrative offence by conducting the concerned activity without having fulfilled the notification duty referred to by [Section 26](#).

(2) A manufacturer or authorised representative established in the Czech Republic, an importer, distributor, servicing person, sponsor of a clinical investigation or notified body shall commit an administrative offence by

- a) providing false data in the fulfilment of the notification duty set forth by [Section 26](#);
- b) failing to notify the Institute of changes to data within the timeline set forth by [Section 29, paragraph 3](#).

(3) An administrative offence shall be penalised by a fine of up to

- a) 1 000 000 CZK, where an administrative offence referred to by paragraph 1 is concerned;
- b) 500 000 CZK, where an administrative offence referred to by paragraph 2, letter a) is concerned;
- c) 200 000 CZK, where an administrative offence referred to by paragraph 2, letter b) is concerned.

Section 84

Administrative offences of legal persons and natural persons-entrepreneurs in medical device notification pursuant to [Section 31](#)

(1) A manufacturer or authorised representative established in the Czech Republic shall commit an administrative offence by

- a) failing to submit to the Institute an application for medical device notification within the timeline set forth by [Section 31, paragraph 1](#);
- b) providing false data in the application for medical device notification filed pursuant to [Section 32, paragraph 2](#); or
- c) failing to submit an application to the Institute within the timeline set forth in [Section 35, paragraph 4](#) upon a change to data specified in the notification.

(2) An administrative offence shall be penalised by a fine of up to

- a) 1 000 000 CZK, where an administrative offence referred to by paragraph 1, letter a) is concerned;
- b) 500 000 CZK, where an administrative offence referred to by paragraph 1, letter b) is concerned;
- c) 200 000 CZK, where an administrative offence referred to by paragraph 1, letter c) is concerned.

Section 85

Administrative offences of legal persons and natural persons-entrepreneurs in medical device notification pursuant to [Section 33](#)

(1) A distributor or importer of a medical device placed on the market in the Czech Republic shall commit an administrative offence by

- a) failing to submit to the Institute an application for medical device notification within the timeline set forth by [Section 33, paragraph 1](#);
- b) failing to notify the Institute of facts referred to in [Section 33, paragraph 2](#);
- c) providing false data in the application for medical device notification filed pursuant to [Section 34, paragraph 2](#); or
- d) failing to submit an application to the Institute within the timeline set forth in [Section 35, paragraph 4](#) upon a change to data specified in the notification.

(2) An administrative offence shall be penalised by a fine of up to

- a) 500 000 CZK, where an administrative offence referred to by paragraph 1, letter a) and b) is concerned;
- b) 200 000 CZK, where an administrative offence referred to by paragraph 1, letter c) and d) is concerned.

Section 86

Administrative offences of legal persons and natural persons-entrepreneurs in the field of distribution, import, dispensing and sale

(1) A distributor shall commit an administrative offence by distributing a medical device contrary to [Section 43, letter a\), b\), c\) or d\)](#).

(2) A distributor or importer shall commit an administrative offence by
a) distributing or importing a medical device contrary to [Section 45, paragraph 1](#); or
b) breaching the rules of good distribution and import practice referred to in [Section 45, paragraph 2](#).

(3) A dispensing person shall commit an administrative offence by
a) breaching any of the obligations set forth by [Section 49](#);
b) breaching an obligation set forth by [Section 50, paragraph 3](#) in mail dispensing;
c) breaching any of the obligations set forth by [Section 54](#);
d) dispensing a medical device contrary to [Section 55, paragraph 1, letter a\), b\), c\) or d\)](#); or
e) failing to safeguard that medical devices excluded from dispensing be stored separately from medical devices which may be dispensed, as referred to by [Section 55, paragraph 2](#).

(4) A seller shall commit an administrative offence by
a) selling a medical device contrary to [Section 56, paragraph 1](#);
b) failing to fulfil any of the obligations set forth by [Section 56, paragraph 2](#);
c) selling a medical device contrary to [Section 57, paragraph 1, letter a\), b\), c\) or d\)](#); or
d) failing to safeguard that medical devices excluded from sale be stored separately from medical devices which may be sold, as referred to by [Section 57, paragraph 2](#).

(5) A legal person or natural person-entrepreneur shall commit an administrative offence by
a) providing a medical device referred to by [Section 46, paragraph 2](#) to the consumer without order;
b) providing a medical device referred to by [Section 46, paragraph 2](#) to the consumer without fulfilling the requirements set forth by [Section 49, paragraph 2](#); or
c) breaching the obligation stipulated by [Section 50, paragraph 2 or 3](#) in medical device mail dispensing.

(6) An administrative offence shall be penalised by a fine of up to
a) 200 000 CZK, where an administrative offence referred to by paragraph 2, letter a), paragraph 3, letter e), and paragraph 4, letter d) is concerned;
b) 500 000 CZK, where an administrative offence referred to by paragraph 1, paragraph 2, letter b), paragraph 3, letter a), c) or d), and paragraph 4, letter a), b) or c), is concerned;
c) 1 000 000 CZK, where an administrative offence referred to by paragraph 3, letter b), or paragraph 5 is concerned.

Section 87

Offences in the field of prescribing

(1) A natural person shall commit an offence by issuing a medical prescription which is an order without being a person referred to in [Section 46, paragraph 1](#).

(2) A natural person, as an employee conducting the medical profession of a medical doctor, shall commit an offence by breaching any of the obligations set forth by [Section 47, paragraph 1 or 2](#)

or [Section 48, paragraph 1](#).

- (3) An offence may be penalised by a fine of up to
- a) 200 000 CZK, where an offence referred to by paragraph 1 is concerned;
 - b) 100 000 CZK, where an offence referred to by paragraph 2 is concerned.

Section 88

Administrative offences of legal persons and natural persons-entrepreneurs in the field of prescribing

(1) A legal person or natural person-entrepreneur shall commit an administrative offence by issuing a medical prescription which is an order without being a person referred to by [Section 46, paragraph 1](#).

(2) A natural person-entrepreneur who conducts the medical profession of a medical doctor shall commit an administrative offence by failure to fulfil any of the obligations set forth by [Section 47, paragraph 1 or 2](#) or [Section 48, paragraph 1](#).

- (3) An administrative offence shall be penalised by a fine of up to
- a) 500 000 CZK, where an administrative offence referred to by paragraph 1 is concerned;
 - b) 100 000 CZK, where an administrative offence referred to by paragraph 2 is concerned.

Section 89

Administrative offences of legal persons and natural persons-entrepreneurs in the field of usage

- (1) A provider of healthcare services shall commit an administrative offence by
- a) using a medical device contrary to [Section 58](#);
 - b) failing to fulfil any of the obligations set forth by [Section 59, paragraph 1, 3 or 4](#);
 - c) failing to safeguard that instructions for use are available to the user as referred to by [Section 60](#);
 - d) using a medical device in the provision of healthcare services contrary to [Section 59, paragraph 2](#);
- or
- e) failing to ensure that
 1. the person operating a medical device is provided with a demonstration referred to in [Section 61, paragraph 1](#);
 2. the demonstration is conducted by a person meeting the requirements stipulated by [Section 61, paragraph 2](#); or
 3. information about any completed demonstrations be maintained and stored pursuant to [Section 61, paragraph 3](#).

- (2) An administrative offence shall be penalised by a fine of up to
- a) 1 000 000 CZK, where an administrative offence referred to by paragraph 1, letter a) or d) is concerned;
 - b) 500 000 CZK, where an administrative offence referred to by paragraph 1, letter b) is concerned;
 - c) 200 000 CZK, where an administrative offence referred to by paragraph 1, letter c) or e) is concerned.

Section 90

Administrative offences of legal persons and natural persons-entrepreneurs in the field of servicing

(1) A provider of healthcare services shall commit an administrative offence by failing to

safeguard the conduct of professional maintenance of the medical device within the scope and frequency stipulated by [Section 65, paragraph 3](#).

(2) A legal person or a natural person-entrepreneur as the servicing person shall commit an administrative offence by failing to fulfil any of the obligations set forth by [Section 65, paragraph 4](#).

(3) A provider of healthcare services shall commit an administrative offence by failing to maintain or store, contrary to [Section 65, paragraph 5](#), records of completed servicing for the mandatory timelines.

(4) A legal person or a natural person-entrepreneur as the servicing person shall commit an administrative offence by failing to safeguard the fulfilment of any of the obligations stipulated by [Section 66, paragraph 2 or 3](#).

(5) An administrative offence shall be penalised by a fine of up to
a) 500 000 CZK, where an administrative offence referred to by paragraph 1, 3 or 4 is concerned;
b) 300 000 CZK, where an administrative offence referred to by paragraph 2 is concerned.

Section 91

Administrative offences of legal persons and natural persons-entrepreneurs in the field of adverse incidents

(1) A manufacturer, authorised representative, distributor, importer, provider of healthcare services, servicing person, dispensing person or seller shall commit an administrative offence by failing to report in writing facts to the Institute within the timeline set forth by [Section 70, paragraph 1 or 2](#).

(2) A provider of healthcare services shall commit an administrative offence by failing to fulfil the obligation set forth by [Section 72, paragraph 1](#).

(3) A provider of healthcare services shall commit an administrative offence by failing to fulfil the obligation set forth by [Section 73, letter b](#)).

(4) A manufacturer or authorised representative shall commit an administrative offence by failing to fulfil the obligation set forth by [Section 74, paragraph 2](#).

(5) A manufacturer shall commit an administrative offence by failing to fulfil the obligation set forth by [Section 74, paragraph 4](#).

(6) An importer, distributor or servicing person shall commit an administrative offence by failing to meet any of the obligations set forth by [Section 75](#).

(7) An administrative offence shall be penalised by a fine of up to
a) 500 000 CZK, where an administrative offence referred to by paragraph 1, 3, or 6 is concerned;
b) 200 000 CZK, where an administrative offence referred to by paragraph 2, 4, or 5 is concerned.

Section 92

Joint provisions governing administrative offences

(1) A legal person and natural person-entrepreneur shall not be liable for an administrative offence if they evidence that they strived to the maximum extent practicable to prevent the breach of the legal obligation.

(2) In the determination of the amount of fine for a legal person or natural person-entrepreneur, the severity of the administrative offence, particularly the way it has been committed and its consequences and circumstances under which it has been committed shall be taken into account.

(3) The liability of a legal person or natural person-entrepreneur shall become void if the administrative authority failed to commence a procedure in respect thereof within two years of the date the latter learnt about it, no later, however, than within five years of the date it was committed.

(4) Administrative offences referred to by this Act shall be managed by the Institute.

(5) Fines shall be collected by the imposing authority.

(6) Income from fines shall be a state budget income.

TITLE XV JOINT, TRANSITIONAL AND FINAL PROVISIONS

Chapter 1 Joint provisions

Section 93 Accessories and other use of medical devices

(1) The provisions of this Act stipulating requirements for medical devices and persons handling medical devices shall be applicable accordingly to medical device accessories and to persons handling thereof.

(2) The requirements set forth for the provision of healthcare services by means of a medical device which are contained in titles VIII, IX, and X, shall be applicable accordingly to persons who provide other than healthcare services by means of a risk class Ia, IIb or III medical device.

Reimbursement of costs Section 94

(1) The applicant shall be obliged to reimburse the costs of performance of expert activities upon request to the Institute. Expert activities shall be considered, in particular, the drafting of expert opinions or assessments.

(2) A person handling medical devices shall be obliged to reimburse the costs of the Institute's activities associated with

- a) authorisation of a clinical investigation and changes to the conditions of a clinical investigation; and
- b) the issue of a free sale certificate.

(3) The amount of reimbursement of costs of expert activities referred to in paragraphs 1 and 2 are stipulated by an implementing legal regulation.

Section 95

(1) A person upon whose request the expert activities are to be conducted shall be obliged to make a reasonable advance payment to the Institute if it is obvious that the expert activities will be performed.

(2) The Institute shall refund to the applicant

- a) the reimbursement of costs in full amount if
 1. the applicant made the reimbursement of costs without being obliged to do so, or
 2. the required expert activity has not been initiated; or
- b) a proportionate part of the reimbursed costs adequate to the expert activities which have not been performed, upon request of the applicant.

(3) Reimbursement of costs referred to by [Section 94](#) shall not constitute a state budget income pursuant to the act governing budgetary rules⁷⁾, it shall be the income of the Institute and shall be maintained on a special account. The Institute shall use these funds solely to cover its activities conducted pursuant to this Act or other legal regulations, unless such activity may be sufficiently covered from budgetary resources.

Chapter 2

Enabling provisions

Section 96

(1) The Government shall issue regulations for the implementation of [Section 5, letter l\)](#), [Section 6, paragraph 1](#), and [Section 24](#).

(2) The Ministry shall issue a decree for the implementation of [Section 6, paragraph 2](#), [Section 19, paragraph 2, letter n\)](#), [Section 45, paragraph 2](#), [Section 46, paragraph 2](#), [Section 48, paragraph 3](#), [Section 56, paragraph 2, letter a\)](#), [Section 59, paragraph 4](#), [Section 71, paragraph 6](#), [Section 74, paragraph 5](#), [Section 78, paragraph 4](#), and [Section 94, paragraph 3](#).

Chapter 3

Transitional provisions

Section 97

(1) A clinical investigation of a medical device initiated prior to the date of the coming into force of this Act and not completed until this date shall be completed and the rights and obligations associated therewith shall be assessed pursuant to current legal regulations.

(2) A provider of healthcare services, for whom an ethics committee for the purposes of conduct of clinical investigations on medical devices has been established prior to the date of coming into force of this Act shall be obliged to send information about the establishment of the ethics committee and its current membership to the Institute within 30 days of the coming into force of this Act.

(3) A person handling medical devices

- a) who notified its operation to the Ministry pursuant to [Section 31, paragraph 2 of Act No. 123/2000 Coll.](#), on Medical Devices and on Amendments to Some Related Acts, shall be considered a person registered pursuant to [Section 26](#). The Ministry shall be obliged to safeguard the hand-over of any notified data to the Registry of Medical Devices no later than within three months of the coming into

force of this Act. The person referred to in sentence one shall be obliged to submit an application for extension of registration to the Institute pursuant to [Section 29](#) within one year of the coming into force of this Act. If the person referred to in sentence one fails to submit the application for extension of registration within one year of the coming into force of this Act, the Institute shall delete the registration of this person from the Registry of Medical Devices;

b) who is subject to the notification duty set forth by [Section 26](#), operates after the date of coming into force of this Act and who, prior to the date of coming into force of this Act, failed to notify its operation pursuant to [Section 31, paragraph 2 of Act No 123/2000 Coll.](#), shall be obliged to submit an application for registration pursuant to [Section 29](#) hereof within the timeline of one year of the date of the coming into force of this Act.

(4) A medical device which has been properly notified by its manufacturer or authorised representative established within the territory of the Czech Republic to the Ministry after 31 March 2011 in compliance with [Section 31, paragraph 1 of Act No 123/2000 Coll.](#), shall be considered a medical device notified in compliance with [Section 31](#). The Ministry shall be obliged to safeguard the hand-over of any notified data to the Registry of Medical Devices no later than within three months of the date of the coming into force of this Act. Within one year of the date of the coming into force of this Act, a manufacturer or authorised representative established within the territory of the Czech Republic shall be obliged to confirm, via the Registry of Medical Device, the validity of the notified data specified in the notification or, if applicable, supplement missing mandatory data set forth by [Section 32](#) and to file an application for extension of notification. If, within one year of the date of the coming into force of this Act, the manufacturer or authorised representative established within the territory of the Czech Republic fails to confirm the validity of data specified in the notification, fails to supplement the mandatory missing data or fails to file an application for extension of notification, the Institute shall delete the medical device from the Registry of Medical Devices.

(5) A distributor or importer who fulfilled its notification duty set forth by Act No [123/2000 Coll.](#) and intends to continue to place on or supply to the market in the Czech Republic a medical device placed or supplied on the market in the Czech Republic thereby prior to the date of the coming into force of this Act and who is subjected to the notification duty pursuant to [Section 33](#) shall be obliged to submit an application for notification of the said medical device no later than within

a) one year of the date of coming into force of this Act, where a risk class III medical device or active implantable medical device is concerned;

b) two years of the date of coming into force of this Act, where a risk class IIb medical device or an *in vitro* diagnostic medical device placed on list A or list B is concerned;

c) three years of the date of coming into force of this Act where a risk class IIa medical device or a medical device intended for self-testing is concerned.

(6) The Institute must decide about the application filed in compliance with paragraph 5 no later than within 90 days of the submission of the application.

(7) Any confirmations of compliance with the requirements governing the placement of medical devices on the market in the Czech Republic or other certificates of a similar nature as the free sale certificate referred to by [Section 37](#) issued by the Ministry prior to the date of coming into force of this Act shall be effective for the period of one year of the date of the coming into force of this Act.

Section 98

(1) A medical device may be dispensed on a medical prescription issued prior to the date of the coming into force of this Act pursuant to current legal regulations.

(2) In case of demonstrations referred to in [Section 61, paragraph 2](#), in respect of a medical device whose manufacturer has ceased to exist, it shall be possible to replace the advice by the manufacturer with the advice by a person who has at least five-year practical experience in the use of the concerned medical device.

(3) A medical device which has not been CE-marked and which has been put in service prior to the date of the coming into force of this Act in compliance with [Section 52 of Act No 123/2000 Coll.](#), may be further used if other conditions stipulated by this Act for the use of medical devices are observed.

(4) For the period of two years of the date of the coming into force of this Act, professional maintenance may be conducted by persons who do not meet the requirements stipulated by [Section 65, paragraph 4, letters a\) and b\)](#), if such activities have been performed by the persons in compliance with Act No [123/2000 Coll.](#) prior to the date of the coming into force of this Act

(5) Investigations of adverse incidents notified to the Institute in compliance with [Section 32 of Act No 123/2000 Coll.](#) shall be completed pursuant to current legal regulations.

(6) A control commenced by the Institute prior to the date of the coming into force of this Act pursuant to [Section 42 of Act No 123/2000 Coll.](#) shall be completed pursuant to current legal regulations.

(7) A control commenced by the Czech Trade Inspection prior to the date of the coming into force of this Act to see whether medical devices are placed on and supplied to the market or put in operation in compliance with technical requirements and whether they are not illegally CE-marked which has not been finalised prior to this date shall be completed pursuant to current legal regulations. Procedures concerning administrative offences committed prior to the date of the coming into force of this Act in the area of medical devices pursuant to the act governing technical requirements for products shall be managed by the Czech Trade Inspection pursuant to current legal regulations.

(8) Procedures concerning administrative offences initiated by the Institute prior to the date of the coming into force of this Act and not finalised prior to this date shall be completed pursuant to current legal regulations.

Chapter IV **Final provisions**

Section 99

(1) If an adequate medical device meeting the requirements of this Act and of the act governing technical requirements for products is not available on the market, the Ministry may, in case of a serious threat to human life or health, exceptionally authorise the use of a medical device not meeting these requirements upon request of a provider of healthcare services; such request must be properly justified. The Administrative Code shall not apply to the decision-making process regarding the authorisation referred to in sentence one.

(2) The authorisation of an exception may not be legally claimed.

Section 100 Confidentiality

(1) Persons who safeguard and conduct clinical investigations of medical devices, members of ethics committees, persons safeguarding and conducting the investigation of adverse incidents, inspectors performing control activities pursuant to this Act, and relevant employees of the Institute and of the Ministry shall be obliged to maintain confidentiality in respect of confidential facts learnt thereby in the fulfilment of their tasks implied by this Act. This shall be without prejudice to the obligations regarding mutual provision of information among public administration authorities and the dissemination of alerts or the obligations of the concerned persons to provide information pursuant to the penal law.

(2) Information

a) pertaining to the registration of persons and notification of medical devices;
b) disseminated by the manufacturer, authorised representative or distributor in relation to measures aimed at the minimisation of adverse incident recurrence; and
c) contained in issued, amended, supplemented, suspended or revoked certificates
shall not be considered confidential facts.

Section 101

This Act has been notified in compliance with Directive [98/34/EC](#) of the European Parliament and of the Council of June 22 1998 laying down a procedure for the provision of information in the field of technical standards and regulations for information society services, as amended.

Chapter 5 Repealing Provisions

Section 102

The following is hereby repealed:

1. Act No [123/2000 Coll.](#), on Medical Devices and on Amendments to Some Related Acts.
2. Part One of Act No [130/2003 Coll.](#), amending Act No [123/2000 Coll.](#), on Medical Devices and on Amendments to Some Related Acts, and some other acts.
3. Part Seventeen of Act No [274/2003 Coll.](#), amending some acts in the field of public health protection, and some other acts.
4. Part One of Act No [58/2005 Coll.](#), amending Act No [123/2000 Coll.](#), on Medical devices and on Amendments to Some Related Acts, as amended, and Act No [455/1991 Coll.](#), on Licensed Trades (Trade Licensing Act), as amended.
5. Part Ninety-Two of Act No [227/2009 Coll.](#), amending some acts in relation to the adoption of the Act on Basic Registries.
6. Act No 196/2010 Coll., amending Act No [123/2000 Coll.](#), on Medical Devices and on Amendments to Some Related Acts, as amended.
7. Part Forty-Eight of Act No [375/2011 Coll.](#), amending some acts in relation to the adoption of the Act on Healthcare Services, Act on Specific Healthcare Services, and Act on the Medical Rescue Service.
8. Government Regulation No [342/2000 Coll.](#), laying down medical devices which may jeopardize the health of man.
9. Government Regulation No [154/2004 Coll.](#), stipulating technical requirements for active implantable medical devices and amending Government Regulation No [251/2003 Coll.](#), amending

some government regulations issued as implementing to Act No [22/1997 Coll.](#), on Technical Requirements for Products and on Amendment to Some Acts, as amended.

10. Government Regulation No [307/2009 Coll.](#), amending Government Regulation No [154/2004 Coll.](#), stipulating technical requirements for active implantable medical devices and amending Government Regulation No [251/2003 Coll.](#), amending some government regulations issued as implementing to Act No [22/1997 Coll.](#), on Technical Requirements for Products and on Amendments to Some Acts, as amended.

11. Government Regulation No [66/2011 Coll.](#), amending Government Regulation No [154/2004 Coll.](#), stipulating technical requirements for active implantable medical devices and amending Government Regulation No [251/2003 Coll.](#), amending some government regulations issued as implementing to Act No [22/1997 Coll.](#), on Technical Requirements for Products and on Amendments to Some Acts, as amended by Government Regulation No [307/2009 Coll.](#)

12. Government Regulation No [336/2004 Coll.](#), stipulating technical requirements for medical devices and amending Government Regulation No [251/2003 Coll.](#), amending some government regulations issued as implementing to Act No [22/1997 Coll.](#), on Technical Requirements for Products and on Amendments to Some Acts, as amended.

13. Government Regulation No [212/2007 Coll.](#), amending Government Regulation No [336/2004 Coll.](#), stipulating technical requirements for medical devices and amending Government Regulation No [251/2003 Coll.](#), amending some government regulations issued as implementing to Act No [22/1997 Coll.](#), on Technical Requirements for Products and on Amendments to Some Acts, as amended.

14. Government Regulation No [245/2009 Coll.](#), amending Government Regulation No [336/2004 Coll.](#), stipulating technical requirements for medical devices and amending Government Regulation No [251/2003 Coll.](#), amending some government regulations issued as implementing to Act No [22/1997 Coll.](#), on Technical Requirements for Products and on Amendments to Some Acts, as amended by Government Regulation No [212/2007 Coll.](#)

15. Government Regulation No [65/2011 Coll.](#), amending Government Regulation No [336/2004 Coll.](#), stipulating technical requirements for medical devices and amending Government Regulation No [251/2003 Coll.](#), amending some government regulations issued as implementing to Act No [22/1997 Coll.](#), on Technical Requirements for Products and on Amendments to Some Acts, as amended, as amended.

16. Government Regulation No [453/2004 Coll.](#), stipulating technical requirements for *in vitro* diagnostic medical devices.

17. Government Regulation No [246/2009 Coll.](#), amending Government Regulation No [453/2004 Coll.](#), stipulating technical requirements for *in vitro* diagnostic medical devices.

18. Government Regulation No [67/2011 Coll.](#), amending Government Regulation No [453/2004 Coll.](#), stipulating technical requirements for *in vitro* diagnostic medical devices, as amended by Government Regulation No [246/2009 Coll.](#)

19. Government Regulation No [223/2012 Coll.](#), amending Government Regulation No [453/2004 Coll.](#), stipulating technical requirements for *in vitro* diagnostic medical devices, as amended.

20. Decree No [316/2000 Coll.](#), on particulars of the final report on a clinical evaluation of a medical device.

21. Decree No [501/2000 Coll.](#), on the forms and methods of reporting adverse incidents of medical devices, their filing, investigation, and evaluation, documentation and its storage and follow-up intended to prevent the occurrence of adverse incidents, in particular their recurrence (Decree on adverse incidents of medical devices).

22. Decree No [304/2003 Coll.](#), amending Decree No [501/2000 Coll.](#), on the forms and methods of reporting adverse incidents of medical devices, their filing, investigation, and evaluation, documentation and its storage and follow-up intended to prevent the occurrence of adverse incidents, in particular their recurrence (Decree on adverse incidents of medical devices).

23. Decree No [356/2001 Coll.](#), on authorisation of exceptions from compliance with technical

requirements for medical devices and their use in the provision of health care and on the scope of publishing of data about their authorisation.

24. Decree No [11/2005 Coll.](#), on types of medical devices with increased risk for users or other parties and on the monitoring of these devices after their placement onto the market.

25. Decree No [100/2012 Coll.](#), on medical device prescribing and on conditions of handling thereof.

PART TWO

Amendment to Act on Administrative Fees

Section 103

Point 3 shall be added to item 97 of Annex to Act No [634/2004 Coll.](#), on Administrative Fees, which shall read:

“3. Acceptance of

a) application for notification or extension of notification of a serially manufactured medical device or accessory of a medical device placed on the market by the manufacture or authorised person

500 CZK

application for change to notification of a serially manufactured medical device or accessory of a medical device placed on the market by the manufacturer or authorised representative

50 CZK

b) notification of operation

of a manufacturer of serially manufactured medical devices

2 500 CZK

manufacturer of custom-made medical devices

2 500 CZK

authorised representative referred to by the Act on Medical devices

2 500 CZK

medical device distributor

2 500 CZK

person servicing medical devices

2 500 CZK

importer of medical devices

2 500 CZK

sponsor of a clinical investigation of a medical device

2 500 CZK

c) application for authorisation of clinical investigation of a medical device

500 CZK

d) application for the issuance of free sale medical device certificate

500 CZK

PART THREE

EFFECT

Section 104

This Act comes into force on 1 April 2015, except for the provisions of Section 9, letter d) and Section 77, which shall come into force as of 1 April 2018.

Hamáček, in his own hand

Zeman, in his own hand

Sobotka, in his own hand

1) Directive [93/42/EEC](#) of the Council of 14 June 1993 on medical devices, as amended. Directive [90/385/EEC](#) of the Council of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, as amended. Directive [98/79/EC](#) of the European

Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic devices, as amended.
Commission Decision [2010/227/EU](#) of 19 April 2010 on the European Databank of Medical Devices (Eudamed).

2) [Section 13, paragraph 3 of Act No 22/1997 Coll.](#), on Technical Requirements for Products and on Amendments to Some Acts, as amended.

3) For example, Communication of the Ministry of Foreign Affairs No [96/2001 Coll. of Min. Comm.](#), on the adoption of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine.

4) Constitutional Act No [110/1998 Coll.](#), on Security of the Czech Republic, as amended by constitutional acts.

5) Constitutional Act No [1/1993 Coll.](#), the Constitution of the Czech Republic, as amended by constitutional acts.

6) Act No [219/1999 Coll.](#), on Armed Forces of the Czech Republic, as amended.

7) [Section 6, paragraph 1 of Act No 218/2000 Coll.](#), on Budgetary Rules and on Amendments to Some Related Acts, as amended.