

WORKING CONSOLIDATED TEXT

**Act No. 123/2000 Coll.,
of 15 April 2000**

**on medical devices and on amendment to some related acts, as amended by Act No.
130/2003 Coll. and Act No. 274/2003 Coll.^{*)}**

The Parliament has adopted this Act of the Czech Republic:

PART ONE

ON MEDICAL DEVICES

Title I

ENACTING PROVISIONS

Article 1

Subject of the Act

The purpose of this Act is to ensure that health care is provided with adequate, safe and efficient medical devices and in such a way that human health shall not be harmed providing that these devices are used correctly for the intended purpose.

Definition of terms

Article 2

(1) Medical device is understood to mean a tool, equipment, aid, instrument, material or any other object or product used independently or in combination, including software equipment, which is designed by the producer or the importer to be used in humans for the following purposes

- a) diagnosis, prevention, monitoring, therapy or palliation of a disease,
- b) diagnosis, monitoring, therapy, palliation or compensation of an injury or disability,
- c) examination, replacement or modification of an anatomical structure or physiological process,
- d) conception control,

and which does not achieve its main intended function in the human body or on its surface through a pharmacological or immunological effect or by affecting the metabolism, while its function can be supported by such effects.

(2) Medical device is also understood to mean a product

- a) designed to administer medication;¹⁾ however, if this product is placed on the market in

^{*)} **Amendments by Act No.274/2003 Coll. are in bold and underlined**

¹⁾ Article 2(1) of Act No.79/1997 Coll., on pharmaceuticals and on amendments to some acts

such a way that the medical device and the medication form one single integral product designed exclusively for a single use in this combination, this product is subject to a special legal regulation.²⁾ The requirements concerning safety and effectiveness of such medical device are stipulated for by special legal regulations,³⁾

- b) containing as its integral part a substance which if used independently can be considered a medication¹⁾ and which exerts its effect on the body in a way that complements the effect of the medical device,
- c) which is a chemical agent, result of a reaction, calibrator, control material, set, tool, instrument, equipment or a system, used independently or in a combination and designed by the producer for in vitro use to examine samples, including donated blood and tissues obtained from the human body, with the objective of obtaining information about the physiological or pathological condition or a congenital anomaly, or to assess their safety and compatibility with possible recipients, or to monitor therapeutic measures (hereinafter referred to as “in vitro medical device”). The in vitro medical device is also understood to mean a vacuum or other container specifically designed by the producer for the primary control and protection of samples obtained from the human body for the purpose of in vitro diagnostic examination. Products of general laboratory use are not in vitro medical devices if they are not specifically designed by the producer for in vitro use with respect to their characteristics.
- d) produced individually on the basis of a medical prescription by means of which the physician issues an independent design of a medical device to be used exclusively by the indicated individual,
- e) designed by the producer for clinical evaluation or clinical testing carried out by a clinical research worker (hereinafter referred to as the “examiner”) in accordance with Articles 8 to 14; the qualification and specialization of a physician⁴⁾ or other qualified individual who shall carry out clinical evaluation or clinical testing must correspond to the
 1. tested medical device, and
 2. the health condition
 - 2.1. of the ill individual (hereinafter referred to as the “patient”) or
 - 2.2. the individual incorporated into a parallel comparison group who will undergo clinical testing voluntarily (hereinafter referred to as the “subject”),
- f) the functioning of which depends on a source of electric or other energy or on a different source of energy other than the energy produced directly by the human body or originating as a result of gravitation, designed for a complete or partial insertion by the physician into the human body and remaining at the place of insertion, even if it is designed for administering medication¹⁾ or contains as its integral part a substance which if used independently can be considered a medication.¹⁾ Such device can also be produced
 1. on order as stipulated for in letter d),

²⁾ Act No.79/1997 Coll.

³⁾ Act No.22/1997 Coll., on technical requirements for products and on amendments to some acts, as later amended.

Act No.102/2001 Coll., on general product safety and on amendments to some acts (act on general product safety), as amended by Act No.146/2002 Coll.

Government Order No.181/2001 Coll., that lays down the technical requirements for medical devices establishing, as amended by Government Order No.336/2001 Coll.

Government Order No.191/2001 Coll., that lays down the technical requirements for active implantable medical devices, as amended by Government Order No.337/2001 Coll.

Government Order No.286/2001 Coll., that lays down the technical requirements for “in vitro” diagnostic medical devices.

⁴⁾ Decree No.77/1981 Coll., on healthcare workers and other professional workers in healthcare, as amended by Act No.425/1990 Coll.

2. for the purpose of clinical testing as stipulated for in letter e),
- g) containing as its integral part a substance which if used independently can be considered a medical preparation or a component of a medical preparation²⁾ originating from human blood or human plasma in accordance with a special legal regulation²⁾ and which can in its effect complement the effect of the product. In such case the product must be assessed and approved as a medical device.

(3) Medical device is also understood to mean a product which is not a medical device according to paragraph 1 but is specifically designed by the producer to be used together with a medical device in such a way as to facilitate its use for the purpose determined by the producer (hereinafter referred to as the “accessory”).

Article 3

For the purpose of this Act it is also understood that

- a) the producer is a person who designs, produces, packages and labels the medical device and is responsible for these activities before placing the device on the market under this person’s own name and surname, company or brand name, and disregarding the fact whether this person performs the listed activities itself or is represented by a third person authorized by the producer in writing to act on his behalf with respect to producer’s obligations stipulated for by this Act and by special legal regulations,³⁾
- b) the distributor is a person defined by a special legal regulation establishing technical requirements for products,⁵⁾
- c) the determined purpose of use is such a use for which the medical device is designed by the producer,
- d) the provider is a person authorized to provide health care,⁷⁾
- e) the user is a patient, provider or other persons who use the medical device for the determined purpose of use,
- f) placing on the market means the moment when a medical device, which is not intended for clinical evaluation or clinical testing according to Article 2(2) letter e), passes, either against a payment or not, for the first time from the phase of production or import into the phase of distribution as goods for sale, disregarding whether it is new or fully renewed,
- g) an adverse event is
1. any failure or deterioration in the properties or effectiveness of a medical device, or any inaccuracy in labeling of a medical device or in its instructions for use, which can or could lead to the death of the user or other individual or to a serious deterioration in their health condition,
 2. any technical or medical fact related to the properties or effectiveness of a medical device which leads to a systematic withdrawal of medical devices of the same type from the market due to reasons specified in point 1,
- h) side effects are undesirable concomitant effects identified during or after the medical device was used in accordance with its determined purpose of use,

⁵⁾ Article 2 of Act No. 22/1997 Coll., as later amended.

⁷⁾ Act No. 20/1966 Coll., on public health, as later amended.

Act No. 160/1992 Coll., on health care in private healthcare facilities, as amended by Act No. 161/1993 Coll.

- i) mutual impact is any undesirable effect that medical devices have on each other or that a medical device has on other objects or medication when used in accordance with its determined purpose of use,
- j) presentation of a medical device is its presentation on trade fairs, exhibitions or for the purpose of advertising (hereinafter referred to as the “presentation”),
- k) the importer is a person defined by a special legal regulation establishing technical requirements for products,⁵⁾
- l) the authorized representative is a person established in a Member State of the European Communities and authorized by the producer in writing to act on his behalf with respect to producer’s obligations stipulated for by this Act and special legal regulations.³⁾

Title II BASIC PRINCIPLES

Article 4

Conditions of use of medical devices

(1) A medical device can be used for its determined purpose of use in the provision of health care

- a) if the conformity of its properties with the technical requirements determined by special legal regulations³⁾ was established in the required way (hereinafter referred to as the “conformity”) with respect to its determined purpose, the device is duly labeled,^{7a)} and the producer or importer issued a declaration in writing to this effect (hereinafter referred to as the “declaration of conformity“), or
- b) if its use by the providers meets the conditions determined by Article 7 and Article 52(2) to (6),
- c) if it is a diagnostic in vitro medical device which the producer did not submit to conformity assessment in accordance with a special legal regulation regulating the placing of the device on the market and putting into service;^{7b)} only a notification of the production, import and export of these devices is delivered to the Ministry of Health (hereinafter referred to as the “Ministry”). This notification must contain instructions for use in the Czech language and describe the way of reviewing the safety, effectiveness and suitability of the device for the provision of health care (who was the reviewer and on the basis of which documents). The fact that the requirements of the previous sentence are met does not affect the obligation to place only safe products on the market.^{7c)}

(2) During the whole time of its use in the provision of health care the medical device must meet the medical and technical conditions determined by the producer. The determined purpose of use of the medical device must be specified in the declaration of conformity and in its instructions for use; if it is technically feasible, it shall also be indicated on the label of the medical device and in advertising materials.

^{7a)} Act No. 22/1997 Coll., as later amended.
Government Order No. 181/2001 Coll., as amended by Government Order No. 336/2001 Coll.
Government Order No. 191/2001 Coll., as amended by Government Order No. 337/2001 Coll.
Government Order No. 286/2001 Coll.

^{7b)} Government Order No. 286/2001 Coll.

^{7c)} Article 3(1) and (2) of Act No. 102/2001 Coll.

(3) Presentation of medical devices for which the declaration of conformity was not issued is allowed only if this fact is clearly stated on their visible labeling. To present these medical devices, the necessary measures for the protection of individuals must be adopted.

(4) The providers must not use medical devices in the provision of health care

- a) if in the light of the findings of medical science there is reasonable suspicion that the safety and health of the users or third persons are at risk, even if the medical device is properly installed or implanted into the human body, maintained and used in accordance with the determined purpose of use,
- b) if the period of their use determined by the producer or importer has expired,
- c) if they show production deficiencies which could cause harm to the health of the users or third persons, or
- d) if the provider does not possess a copy of the assurance in writing that the producer or importer issued the declaration of conformity for these devices in accordance with a special legal regulation^{7d)}, except for cases listed in Article 7 and Article 52(2) to (6), requirements determined by a special legal regulation^{7b)} and cases when this assurance is not issued.^{7e)}

(5) The Ministry can at its own discretion or following a motion by the State Drug Control Institute (hereinafter referred to as the “Institute”), the State Nuclear Safety Office, the Czech Metrology Institute, the Czech Trade Inspection, authorized bodies and accredited persons ban or limit the use in health care of those medical devices which although duly put into service and statutorily maintained and used can nevertheless have an adverse effect on the health or safety of the users or other persons.

(6) The Ministry informs the Commission of the European Communities about any measures adopted in pursuit of the provisions of the above paragraph 5.

Article 5

Protection against risks

(1) If the Ministry obtains information about any of the cases listed in Article 4(4), it shall immediately notify in writing the Czech Office for Standards, Metrology and Testing (hereinafter referred to as the “Office”), the Czech Trade Inspection and providers about the imminent danger; a warning to general public is acceptable if there are risks from delay and if no other, equally efficient measures could have been implemented.

(2) The Ministry will inform the Czech Trade Inspection in writing about the occurrence of an adverse event immediately after obtaining information specified in Article 32(4).

Article 6

(1) The obligations of the producer also apply to the person who assembles, packages, processes, adjusts or labels the medical device and determines the purpose of its use with the

^{7d)} Article 13(9) of Act No. 22/1997 Coll., as later amended.

^{7e)} Act No. 22/1997 Coll., as later amended.

intention of placing it on the market under this person's own name and surname, company or brand name; producer's obligations do not apply to the person who only assembles or adjusts medical devices which are already on the market for the determined purpose of use for a particular patient.

(2) In case of any unclear issues related to clinical evaluation or clinical testing the Ministry issues its finding. In case of any dispute between the producer or importer and the person authorized to apply classification rules according to a special legal regulation^{9a)} the finding is issued by the Office following an initial statement from the Ministry.

(3) The instructions for use of the medical device, and if feasible and useful then also its label, must contain the name, surname and permanent residence or place of business operations of the producer or importer responsible for the first placing of the medical device on the market if this producer or importer is a physical person, or the company or brand name and seat if the producer or importer responsible for the first placing of the medical device on the market is a legal person.

(4) The way of payment for the medical devices and the amount covered by means of public health insurance are determined by a special legal regulation.¹¹⁾

Article 7

Granting of exceptions

(1) In case of a serious risk of death or damage to health, and if no adequate medical device meeting the requirements of special legal regulations³⁾ is available on the market, the Ministry can as an exception authorize upon receipt of provider's application the use of a medical device which does not meet the requirements of the special legal regulations.³⁾ If such medical device uses nuclear energy or ionizing radiation the Ministry can grant the exception on the basis of approval by the State Nuclear Safety Office.

(2) The Ministry shall determine the details of the application by decree.

(3) There is no legal entitlement to the exception being granted.

(4) The applicant shall be notified about the authorization or rejection.

(5) The fact that an exception is granted is published in the Bulletin of the Ministry of Health of the Czech Republic. The Ministry shall determine the scope of the published information by decree.

Title III

CLINICAL EVALUATION AND CLINICAL TESTING

^{9a)} Annex No. XVI to Government Order No. 181/2001 Coll.

¹¹⁾ Act No. 48/1997 Coll., on public health insurance and on the amendments to some acts, as later amended.

Article 8

General provisions

(1) Medical device must be suitable for use in the provision of health care; suitability of a medical device for the determined purpose of use must be verified by means of clinical evaluation or clinical testing, except for

- a) in vitro medical devices,
- b) medical devices placed on the market in the European Communities Member States and bearing the CE conformity marking.

(2) Clinical evaluation of a medical device (hereinafter referred to as the “clinical evaluation”) is understood to mean its expert evaluation by an examiner on the basis of the available professional publications, technical documentation and other documents in writing in order to review the safety of its use in the provision of health care and to respect the determined purpose of use specified by its producer. If the clinical data and experience with the medical device have already been sufficiently and credibly documented to a necessary extent, only a clinical evaluation is required. The necessary clinical data is obtained from

- a) the description of methodology and results of clinical testing of the medical device, including clinical testing on animals,
- b) published clinical studies, especially
 1. randomized (where the random recruiting for experimental and control groups is based on pre-established criteria such as age and sex, is comparable in basic parameters and cannot be applied retroactively on the basis of the already obtained results) controlled studies,
 2. various types of evaluable non-randomized studies, e.g. cohort studies (carried out in groups of individuals selected on the basis of certain common characteristics, a group exposed to the envisaged risk and a group not exposed to the envisaged risk, both groups are monitored and compared during a determined period of time, especially in the long-term; selection can be retroactive), multi-cohort (multiple cohort studies) or open controlled cohort studies,
 3. case studies,
 4. reports on controlled use of the medical device, after the obligation to notify stipulated for by this Act has been met,
- c) background research or other evaluation of literary data published in the available national or foreign databases, or
- d) data available from other persons, e.g. health insurance companies, bodies responsible for surveillance (vigilance), professional associations.

(3) Clinical testing of a medical device (hereinafter referred to as the “clinical testing”) is understood to mean its systematic testing in accordance with its determined purpose of use and in the conditions determined by the producer carried out by an examiner following a pre-established plan of clinical testing, consisting in the application of the device in individuals in order to

- a) prove whether the medical device is suitable for use in health care in accordance with its determined purpose of use, especially in terms of its safety and effectiveness,
- b) identify its effects on the subject,
- c) identify its adverse side effects and assess whether they represent risks which are acceptable for the subject.

(4) The plan of clinical testing is understood to mean a document containing detailed information about the reasons, purpose, objectives, methods, control and monitoring of clinical testing. The plan must be drafted in accordance with the most recent scientific and technical knowledge and must be structured in such a way as to ensure that the obtained results of clinical testing will unambiguously show the level of safety and effectiveness of the medical device. The plan of clinical testing is binding for all participants of clinical testing.

(5) The person ordering clinical evaluation or clinical testing (hereinafter referred to as the “ordering party”) is responsible for the start, management, organization, inspection or funding and also for any damage caused as a result of the special nature of the clinically tested medical device. The ordering party can fulfill some of its tasks defined in Article 13 through an assistant, with whom it shall conclude an agreement for that purpose. The agreement shall stipulate for their mutual relations and determine the assistant’s responsibilities, e.g. supervision of clinical testing, verification of the availability of the required number of subjects during the whole testing period, supply of material and technical equipment and reporting on the progress of testing to the ordering party.

(6) The examiner is appointed to carry out clinical evaluation or clinical testing by the ordering party or by the provider who is examiner’s employer; in case of clinical testing the examiner is responsible for the involved activities as well as the subjects’ health condition.

(7) Chief examiner is the examiner charged by the ordering party with coordination of activities of the clinical testing carried out on several workplaces.

Article 9

Ethical Commission

(1) The Ethical Commission is appointed by the provider accredited for clinical testing according to Articles 15 and 16, or by the Ministry. It consists of healthcare workers⁴⁾ and other members and must have a minimum of 5 members. The chairman and other members of the Ethical Commission are appointed and recalled by the provider’s statutory body; the chairman and other members of the Ethical Commission established by the Ministry are appointed and recalled by the Minister of Health. Only individuals with no criminal convictions and without personal interest or involvement in the execution of the clinical testing are eligible to become members of the Ethical Commission. An individual with no criminal convictions is understood to mean an individual who has not been effectively convicted of a deliberate criminal act committed in relation to clinical testing or clinical evaluation or in relation to the provision of health care; integrity shall be proved by means of excerpt from the Criminal Register.

(2) Meetings of the Ethical Commission are oral and private, neither the ordering party or its assistant nor the examiner shall participate in the adoption of Ethical Commission’s decisions. Voting in the Ethical Commission is open, each member having one vote. An absolute majority of votes of all members is required to adopt an Ethical Commission’s decision; the chairman’s vote is decisive in case of an equal vote.

(3) The provider shall report the establishment of an Ethical Commission to the Ministry within 30 days of its establishment. Ethical Commission issues a written approval of clinical testing of the medical device and supervises its progress in terms of safety and observance of

the subjects' rights. For this purpose it assesses especially the professional qualification of examiners, including the chief examiner, suitability of the involved equipment, procedures and groups of subjects, and does so independently of the ordering party, examiner or administrative or other bodies.

(4) The ordering party is obliged to notify the corresponding Ethical Commission in advance and in writing of its intention to carry out clinical testing; the ordering party will submit the documentation specified in Article 12(2) letter a), except for point 4, attached to this notification. The Ethical Commission will either grant its approval or inform the ordering party about the rejection of clinical testing within 60 days of the receipt of the notification. The time elapsed between the Ethical Commission's request for the missing documents to be supplied and their delivery by the ordering party does not count as part of that 60-day period.

(5) If the conditions of clinical testing approved by the Ethical Commission need to be changed, the examiner or the ordering party shall ask the corresponding Ethical Commission for a written approval of the changes in the conditions of clinical testing and shall submit to the Ethical Commission a proposal for amendment of the documentation.

(6) The Ethical Commission shall revoke in writing its approval of execution of clinical testing if

- a) new facts arise which have a negative impact on subjects' safety, providing that these facts cannot be immediately eliminated, or
- b) the ordering party or the examiner, including the chief examiner, are in a major breach of their obligations.

(7) Details of the establishment and composition of Ethical Commission, methods of protection of the subjects' personal data, and the template of the Commission's rules of procedure may be determined by the Ministry by decree; in that case the Ministry shall take care that the independence of Ethical Commission is not affected.

(8) The Ethical Commission files all important records of its activity, especially the operation protocols in writing, list of members with their qualifications, submitted requests for approval of the start of clinical testing, documentation, minutes of meetings, reports and correspondence related to clinical testing for the period of at least 10 years after completion of the clinical testing in the provider's facility. If the Ethical Commission ceases to exist, the provider is responsible for the storage of its documentation; if the documents were submitted to an Ethical Commission established by the Ministry, the Ministry is responsible for their storage.

(9) If the Ethical Commission of the provider where clinical testing is carried out ceases to exist, the statutory body of that provider shall immediately inform the Ministry to this effect and ensure that the documentation of clinical testing is handed over to an Ethical Commission established by the Ministry, which shall thereafter execute the functions of the Ethical Commission which ceased to exist.

Article 10

Informed consent

(1) Informed consent is understood to mean a voluntary and demonstrable expression of the subject's or his/her legal representative's will to undergo clinical testing, provided under conditions specified in paragraph 2; the subject must be informed about these conditions in advance.

(2) Information must be provided in writing, understandably and in a language which the subject understands well; it forms part of the informed consent and must contain

- a) adequate information about clinical testing, including its objective,
- b) information about possible benefits of clinical testing for the subject,
- c) information about predictable risks and possible inconveniences related to clinical testing,
- d) information about other applicable therapeutic or diagnostic methods,
- e) information about the management of confidentiality of the obtained data related to the subject, and the fact that persons who were not acquainted with this data in the course of clinical testing can be granted access to it only with the subject's prior consent,
- f) rights and obligations of the subject, including
 1. subject's right to withdraw from clinical testing at any time and information about the way and consequences of such withdrawal,
 2. the entitlement to reimbursement of indispensable travel expenses¹⁴⁾ and reimbursement of the demonstrated earnings (profit) lost due to subject's participation in clinical testing, and
 3. the entitlement to damages in case of harm to the subject's health resulting from the fact that the subject underwent clinical testing.

(3) Informed consent must be valid during the whole time of duration of the clinical testing; if the subject withdraws his/her consent clinical testing must be discontinued.

(4) If new facts relevant to the informed consent arise, the subject must be informed about these facts by the examiner without delay. Information provided in pursuit of the provision of this paragraph must comply with the provisions of paragraphs 1 to 3.

Article 11

Conditions of clinical testing

(1) Clinical testing on subjects can start and proceed only if

- a) the predictable risks and inconveniences do not outweigh the expected benefits to the subject or public health protection,^{14a)}
- b) informed consent was obtained from the subject or subject's legal representative immediately before the start of clinical testing,
- c) written approval of the plan of clinical testing was obtained from the Ethical Commission of the provider where the clinical testing is to be carried out or from the Ethical Commission established by the Ministry if the provider's Ethical Commission was not established,
- d) it starts and proceeds under the management of an examiner, who is
 1. a physician with adequate qualification and specialization for that purpose, or
 2. another individual qualified for that purpose,

¹⁴⁾ Act No. 119/1992 Coll., on reimbursement of travel expenses, as later amended.

^{14a)} Article 2 of Act No. 258/2000 Coll., on the protection of public health and amendment of some related acts.

and in a suitable environment, within the limits of the determined purpose of use of the medical device and under the conditions determined by the producer,

- e) whenever applicable
 - 1. the biological safety test in accordance with the current level of scientific knowledge or any other test required for the verification of the determined purpose of use of the medical device was carried out, and
 - 2. the suitability of use of the medical device in terms of safety and technical standards was proved with respect to its technical condition, regulations governing health and safety at work and regulations in the area of prevention of work injuries, and
 - 3. ethical principles were observed,^{14b)}
- f) the examiner was informed about the results of tests listed under the letter e), as well as about the possible risks related to the execution of clinical testing,
- g) the persons involved in the design, approval, execution, inspection, recording and evaluation of clinical testing
 - 1. have adequate qualification to fulfill their tasks, and
 - 2. will not exert inadequate influence on the subject,
- h) contracts and agreements closed within the framework of clinical testing were documented in writing and signed by their contracting parties,
- i) insurance was procured covering eventual damage to the health of the subjects or third persons in the course of clinical testing; the premium must also cover cases when no particular person is found responsible for the inflicted damage.

(2) Clinical testing which does not foresee any preventive or therapeutic benefit to the subject must not be carried out on subjects

- a) whose legal capacity was disabled or limited,
- b) whose informed consent cannot be obtained due to their health condition,
- c) in custody or serving their term of imprisonment or subjects placed in any other facilities on the basis of a court ruling,
- d) doing their basic military service, substitute service or alternative civil service, or
- e) who receive health care without having consented to it.

(3) Clinical testing in individuals under 18 years is carried out under the conditions specified in paragraph 1 only providing that

- a) according to the current knowledge of the medical science
 - 1. the determined purpose of use of the medical device is the establishment of diagnosis and protection of health (especially prevention of diseases) in these subjects, or
 - 2. clinical testing in subjects older than 18 years would not bring satisfactory results.
- b) the subject's legal representative gave his/her informed consent in writing; if the subject is able to understand to a sufficient extent the nature, importance and impact of the clinical testing and on the basis of this ability is able to decide freely and express this decision in writing, his/her informed consent in writing must also be obtained.

^{14b)} For example the principles established by the Helsinki Declaration adopted by the 18th World Health Convention in 1964 in Helsinki, Finland, amended and extended by the 29th World Medical Assembly in Tokyo in 1975, the 35th World Medical Assembly in Venice in 1983 and the 41st World Medical Assembly in Hong Kong in 1989, in Somerset West in the Republic of South Africa in 1996 and in Edinburgh in 2000, and by the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine.

(4) Clinical testing in pregnant or breast-feeding women is carried out under the conditions specified in paragraph 1 only providing that according to the current knowledge of the medical science

- a) the determined purpose of use of the medical device is the protection of health (especially the prevention of the development of a disease), establishment of diagnosis, treatment of a disease or its palliation, either in pregnant or breast-feeding women or as yet unborn children,
- b) the execution of clinical testing bears only a minimum risk for the unborn child, and
- c) there is a justified conviction that satisfactory results of clinical testing can only be achieved if the testing is carried out on subjects that are either pregnant or breast-feeding women.

(5) Clinical testing must use procedures adequate to the tested clinical device; in the event of unexpected or increased risks to the subjects the testing must be interrupted and if these risks cannot be eliminated, the testing must be stopped. The following bodies must be notified in writing about the intention to carry out clinical testing before the testing starts:

- a) the Ministry, or
- b) the corresponding authority of the European Communities Member State in which the clinical testing is to be carried out.

In case of medical devices specified by a Government Order testing can start after the expiry of 60 days from the day of notification, providing that rejection of testing on the grounds of protection of the subject's health or in public interest was not communicated within this period; the rejection is communicated in writing to the ordering party or its authorized representative and also to the provider, the corresponding Ethical Commission and the Institute.

(6) The duration of clinical testing and the frequency of monitoring must correspond to the nature of the tested medical device, its determined purpose of use, its declared safety, suitability and effectiveness, in order to ensure the validity of expert conclusions.

Article 12

Clinical evaluation and clinical testing records

(1) The records of clinical evaluation consist mainly of

- a) the written agreement between the ordering party and the provider in whose facility the evaluation is to take place,
- b) written agreement between the ordering party (ordering party's assistant) and the examiner (examiners), stipulating for example for their relations of obligation and confidentiality according to Article 49,
- c) set of relevant information known before the start of the clinical evaluation,
- d) set of documents containing the necessary data on the medical device to be evaluated, and
- e) the final report of clinical evaluation.

(2) The records of clinical testing consist mainly of

- a) before the start of clinical testing
 - 1. agreements specified in paragraph 1 letters a) and b),

2. examiner's manual, which is understood to mean a set of relevant information known before the start of clinical testing, especially information harmonized with the law and recommendations of the European Communities,^{14c)}
 3. the plan of clinical testing,
 4. written approval by the Ethical Commission,
 5. informed consent,
 6. set of documents containing the necessary data on subjects and on the medical device to be clinically tested; these documents form part of the plan of clinical testing,
 7. list of medications and the way of their administration to subjects,
 8. method of compensation for eventual damage to a subject's health resulting from the fact that the subject is undergoing clinical testing,
- b) in the course of clinical testing, records of
1. activities carried out in accordance with the plan of clinical testing,
 2. unexpected developments and measures implemented beyond the plan of clinical testing,
 3. adverse events, if applicable,
- c) the final report of clinical testing after the testing is completed includes especially the description of methodology and design of clinical testing, analysis of all collected data from the participating workplaces including critical evaluation and the corresponding statistical analysis, and data on all subjects while no subject must be identifiable on the basis of this report or the published results.

Article 13

Ordering party's obligations with respect to clinical evaluation or clinical testing

(1) The party ordering clinical evaluation is obliged to

- a) secure an examiner who must
 1. have the corresponding qualification, experience and knowledge of use of the particular medical device,
 2. be authorized to perform the corresponding professional activity,
- b) ensure that documents, especially the final report of clinical evaluation, are drafted, stored, safe and complete,
- c) ensure that agreements specified in Article 12(1) letters a) and b) are concluded in writing,
- d) provide the examiner with instructions, manuals or training focused on the determined purpose of use of the medical device, and technical and other data about the evaluated medical device,
- e) arrange for the final report of clinical evaluation to be signed by the statutory body of the provider where the clinical evaluation was carried out, as well as by the examiner and the statutory body of the ordering party.

(2) The party ordering clinical testing is obliged to

^{14c)} Council Directive No. 93/42/EEC of 14 June 1993, on medical devices, as amended by Council Directive 98/79/EC of 27 October 1998.
CSN EN 540 "Clinical evaluation of medical equipment for humane purposes of 21 June 1993".

- a) secure an examiner who must
 1. have the corresponding qualification, experience and knowledge of use of the particular medical device,
 2. be authorized to perform the corresponding professional activity,
 3. be familiar with the clinical environment in which the clinical testing should take place, as well as with the conditions and requirements on clinical testing,
- b) ensure that documents are drafted, stored, safe and complete, especially
 1. the plan of clinical testing,
 2. reports on subject examinations,
 3. approval of the Ethical Commission according to Article 9(3),
 4. information on adverse events that were reported to the ordering party,
 5. final report of clinical testing,
 6. other documents containing data, statistical analyses, results of tests carried out in accordance with Article 11(1) letter e), including data processed by the persons participating in the clinical testing,
- c) ensure that agreements stipulated for by Article 12(2) letter a) point 1 are concluded in writing,
- d) ensure that examiners are notified in writing about adverse events in clinical testing carried out on several workplaces, and must do so within 10 days of being informed about these adverse events.

(3) In the execution of clinical testing the ordering party is also obliged to

- a) agree with the examiner on
 1. the collection and evaluation of statistical data,
 2. number of subjects, and
 3. methods and procedures of recording and analyzing adverse events,
- b) charge the ordering party's assistant with supervision of the execution of clinical testing; the ordering party does not have this obligation if it shall itself supervise and bear responsibility for the clinical testing,
- c) provide the examiner with
 1. a manual in writing, and possibly other data necessary for the execution of the particular clinical testing,
 2. instructions, manuals or training focusing on the determined purpose of use of the medical device,
 3. technical and other data about the tested medical device, and
 4. information obtained in pre-clinical testing related to the object of clinical testing; documents listed in points 1 to 3 must be in the Czech language,
- d) sign
 1. the plan of clinical testing,
 2. the final report of clinical testing,
- e) hand the medical device to be clinically tested and identified in the plan of clinical testing over to the examiner,
- f) store records of adverse events reported to the ordering party in the course of clinical testing for a minimum of 15 years,
- g) evaluate adverse events in cooperation with the examiner and report them to the Institute as they occur; the Ministry can determine the content of such report by decree,

- h) contract damage liability insurance stipulated for by Article 11(1) letter i) with a licensed insurance company.¹⁵⁾ The scope of the insurance must adequately reflect the risks related to the particular clinical testing and the insurance against death or permanent damage to health or long-term inability to work must be covered up to at least 1 000 000 CZK. The agreed amounts are subject to indexation by 6% every 12 months starting from the day of validity of the insurancecontract. The entitlement to damages ceases to exist as soon as funds are drawn to cover the insured events,
- inform the Ministry in writing before the start of clinical testing^{14c)} about the intention to carry out clinical testing in accordance with the corresponding plan of clinical testing and about the approval by the Ethical Commission; the plan of clinical testing and approval of the Ethical Commission shall be attached to the document by which the Ministry is informed.

Article 14

Examiner's obligations in clinical evaluation and clinical testing

- (1) For the purpose of clinical evaluation the examiner is obliged to
- a) acquaint himself to an adequate extent with the materials related to the medical device according to Article 8(2) with respect to its determined purpose of use,
 - b) declare in writing that the examiner and his co-workers will be able to perform and complete the clinical evaluation. The examiner is also obliged to demonstrably declare that neither the examiner nor his co-workers have any personal relation to the object of clinical evaluation which could give rise to a conflict of interests or have a negative impact on the clinical evaluation with the execution of which they are charged, especially if it is executed simultaneously to another clinical evaluation in which they are personally involved,
 - c) sign the final report after the clinical evaluation is completed, and
 - d) store the records listed in Article 12(1) for the period of 10 years.
- (2) For the purpose of clinical testing the examiner is obliged to
- a) ensure that the subject shall not be exposed to the risks involved in the execution of clinical testing,
 - b) ensure evaluation whether subject's health condition makes it possible to start clinical testing,
 - c) ensure that informed consent is obtained,
 - d) ensure that the plan of clinical testing is drafted and submitted to the Ethical Commission and that the Ethical Commission's ruling is delivered to the ordering party; the examiner is also responsible for information to be provided to the Ethical Commission concerning
 1. the scientific basis of the proposed plan with respect to pre-clinical data,
 2. possible impact on subjects' health, its risks and possibilities of their reduction,
 3. the expected mental state of the subjects,
 4. proposed method of inspection of clinical testing and the scope of examiner's responsibility,
 5. any financial or other offer made to the subjects,

¹⁵⁾ Act No. 363/1999 Coll., on insurance business and on amendments to some acts (the Insurance Act), as later amended.

6. content of agreements concluded between the ordering party and the examiner,
 7. method of obtaining informed consent from the subject or his/her legal representative,
 8. insurance contracted according to Article 13(3) letter h),
 9. other relevant information not specified in the plan of clinical testing,
- e) ensure accuracy, legibility and protection of the data on clinical testing in the documents and records on subjects both during clinical testing and after its completion,
 - f) ensure any changes in data specified in letter e); these changes must be made in such a way so as to leave the original entry legible and must bear the date when they were made and the signature of the person who made them,
 - g) ensure that adverse events are reported to the ordering party, documented and that their negative effects on the health of the subjects or other individuals involved in clinical testing are eliminated.

(3) With respect to clinical testing the examiner is also obliged to

- a) before the start of clinical testing
 1. request from the ordering party the examiner's manual or other information which he considers indispensable for the execution of clinical testing,
 2. acquaint himself to an adequate extent with the use of the medical device in accordance with its determined purpose of use,
 3. acquaint himself properly with the plan of clinical testing and sign it,
 4. draft a statement declaring that the examiner and his co-workers will be able to perform and complete the clinical testing and that neither the examiner nor his co-workers have any personal relation to the object of clinical testing which could give rise to a conflict of interests or have a negative impact on the clinical testing with the execution of which they are charged, especially if other clinical testing in which they are personally involved is being carried out at the same time,
 5. ensure that the necessary preparations are made, including measures to be applied later in the testing in case that unexpected situations, including adverse events, emerge,
 6. ensure that the health condition of subjects in which no direct therapeutic benefit can be expected is evaluated and sign their examination report, and
 7. demonstrably inform the subject about his/her health condition, possibly also about the prescribed medication and way of its administration,
- b) in the course of clinical testing
 1. arrange for an adequate selection of subjects, register the subjects according to their participation in clinical testing, keep a record of their addresses, telephone contact numbers or other way of communication, and of the medical report on each subject's health condition,
 2. inform the subject's attending physician about the subject's involvement in clinical testing,
 3. inform the subject about the possible consequences to his/her health in case of withdrawal from clinical testing if the subject has made a decision to this effect in the course of testing,
 4. inform the Ethical Commission about any changes in the plan of clinical testing, once they were approved by the ordering party, and ask for the commission's position,
 5. immediately inform the ordering party or the ordering party's assistant, the corresponding Ethical Commission, the Institute and the Ministry about the occurrence of any adverse events and about the adopted measures,
 6. discuss with the ordering party any adjustments to the plan of clinical testing; no adjustments can be made without the ordering party's written approval. This does not

apply in case of a critical situation developing towards the risk to a subject's health, in which case the deviations from the plan of clinical testing do not require prior approval by the Ethical Commission or the ordering party and are not considered a breach of agreement, but have to be reported to the ordering party, and

7. check whether all actions comply with the plan of clinical testing and whether the persons executing and arranging for the clinical testing duly fulfill the tasks that he has delegated to them,
- c) after the completion of clinical testing
1. sign the final report of clinical testing; if the examiner refuses to do so, he must provide relevant explanation of his reasons for such refusal, and
 2. store for a period of 10 years the records specified in Article 12(2) letters b) and c), in such a way as to ensure that without the subject's prior consent his/her identity shall not become known to any persons who were not acquainted with these records in the course of the clinical testing.

Qualification for performance of clinical evaluation or clinical testing

Article 15

(1) Assessment of the capacity of the provider's facility (hereinafter referred to as the "workplace") to perform clinical evaluation or clinical testing is a procedure in which the Ministry evaluates whether the system of basic satisfaction of the material, technical and staff requirements at the provider's workplace¹⁶⁾ is fit for performance of clinical evaluation or clinical testing of a particular medical device.

(2) If the workplace

- a) is found qualified for the performance of clinical evaluation or clinical testing, the Ministry shall issue an accreditation for the performance of clinical evaluation or clinical testing (hereinafter referred to as the "accreditation"),
- b) is not found qualified for the performance of clinical evaluation or clinical testing, the Ministry shall reject the application for accreditation.

(3) After consultations with the corresponding Chamber¹³⁾ the Ministry can determine by decree in more detail the material, technical and staffing conditions required for accreditation of a workplace.

(4) The cost of accreditation of the provider's workplace for the performance of clinical evaluation or clinical testing is born by the corresponding provider.

Article 16

(1) The accreditation specifies the object, scope and conditions under which clinical evaluation or clinical testing may be performed, and the period for which the accreditation is issued.

¹⁶⁾ Decree No. 49/1993 Coll., on the technical and material requirements for the equipment of healthcare facilities, as later amended.

¹³⁾ Act No.220/1991 Coll., on the Czech Chamber of Physicians, the Czech Stomatological Chamber and the Czech Chamber of Pharmacists, as later amended.

(2) The Ministry reviews compliance with the requirements with respect to which the accreditation was issued; if any deficiencies are identified and depending on their gravity the Ministry shall either temporarily suspend the validity of the accreditation, or revoke it completely.

(3) Notice of the issued and revoked accreditations shall be published by the Ministry in the Bulletin of the Ministry of Health of the Czech Republic.

TITLE IV PRESCRIPTION AND DISPENSATION OF MEDICAL DEVICES

Article 17

Prescription of medical devices

(1) The Government shall by its order identify medical devices which can pose a direct or indirect risk to human health even when used in accordance with their determined purpose of use if their use is not supervised by a physician or if it requires consultation with a physician, establishment of diagnosis by a physician, or treatment according to the instructions and under the supervision of a physician, or devices that are often and to a great extent used contrary to their determined purpose of use; such medical devices are prescribed by means of the medical device voucher form¹⁷⁾ (hereinafter referred to as the “voucher”) or on order.

(2) When prescribing medical devices

- a) in the Army of the Czech Republic the provisions of this Act and of a special legal regulation¹⁸⁾ are followed,
- b) in the Police of the Czech Republic the provisions of this Act and of a special legal regulation¹⁸⁾ are followed. Inspection of the above activities is the responsibility of the bodies of the Ministry of Interior,
- c) in the Prison Service of the Czech Republic the provisions of this Act and of a special legal regulation¹⁸⁾ are followed.

Article 18

Sale of medical devices

(1) In addition to the producer, distributors, pharmacies, other facilities appointed to provide medical devices¹⁹⁾ and other legal or physical persons defined by a special legal regulation,^{19a)} medical devices identified by decree according to paragraph 2 can also be

¹⁷⁾ Decree No. 61/1990 Coll., on drug and medical products management, as later amended.

¹⁸⁾ Article 80(1) of Act No. 20/1966 Coll., as amended by Act No. 548/1991 Coll.

¹⁹⁾ Article 20(1) and Article 37 of Act No. 20/1966 Coll., as later amended.

Article 10(3) letter e) of Act No. 160/1992 Coll., as later amended.

^{19a)} Article 17(13) letter a) of Act No. 48/1997 Coll., as later amended.

bought, stored and sold to customers^{19b)} by physical or legal persons who obtained business license for this activity in accordance with a special legal regulation²⁰⁾ (hereinafter referred to as the “sellers of medical devices”). The sellers of medical devices must have the corresponding education or demonstrate two years’ experience in work with medical devices and must be trained by the producers of the corresponding medical devices for the activities specified in the first sentence.

- (2) The Ministry can identify by decree
- a) medical devices which
 - 1. can be sold by the sellers of medical devices,
 - 2. cannot be sold in self-service, vending machines or through home delivery service or computer networks, and
 - 3. can only be sold to distributors and providers, healthcare workers⁴⁾ and other legal or physical persons identified by a special legal regulation,^{19a)}
 - b) basic conditions of storage and sale of medical devices.

Article 19

Obligations related to sale of medical devices

(1) The activity of producers, distributors, other physical or legal persons identified by a special legal regulation^{19a)} and sellers of medical devices in cases when medical devices are delivered to providers, with the exception of pharmacies and other healthcare facilities appointed to dispense and sell medical devices,¹⁹⁾ is considered as supply of medical devices to the providers.

(2) Producers, distributors, other legal or physical persons identified by a special legal regulation,^{19a)} pharmacies, other facilities appointed to provide medical devices¹⁹⁾ and the sellers of medical devices are obliged to

- a) handle the medical devices in accordance with their instructions for use or producer’s instructions, if the producer does not determine otherwise,
- b) immediately report to the Institute the occurrence of any adverse event or emergence of any fact leading to a reasonable belief in the occurrence of an adverse event as soon as it becomes known to them.

(3) Pharmacies, other facilities appointed to provide medical devices,¹⁹⁾ other legal or physical persons identified by a special legal regulation^{19a)} and persons supplying medical devices according to paragraph 1 are obliged to store for the period of 10 years for the needs of the corresponding administrative bodies copies of the vouchers or purchase orders on the basis of which the medical devices specified in Article 17(1) and Article 20(3) letters a) and b) were sold.

(4) Persons supplying medical devices to healthcare facilities according to paragraph 1 are obliged to store for the period of 10 years for the needs of the corresponding administrative bodies copies of the purchase orders on the basis of which the medical devices specified in Article 17(1) and Article 20(3) letters a) and b) were sold.

^{19b)} Article 2(1) letter a) of Act No. 634/1992 Coll., on customer protection, as later amended.

²⁰⁾ Act No. 455/1991 Coll., on trading activities (Trading Act), as later amended.

TITLE V
INSTALLATION, USE, MAINTENANCE, SERVICING AND REGISTRATION OF
MEDICAL DEVICES

Article 20

General obligations

- (1) Providers are obliged to ensure that
- a) medical devices are installed, used and maintained only for the determined purpose of use and in accordance with the rules of operation and regulations stipulating for the safety and protection of health at work,
 - b) medical devices are connected for a combined use with other medical devices, accessories, the necessary software or other objects only if this connection complies with letter a) in terms of safety and is required for their proper functioning,
 - c) medical devices are used only by individuals who on the basis of their adequate education, other knowledge, practical experience and if applicable also specific training in the use of a particular medical device or group of devices provide the guarantee of expert use of these devices in accordance with their instructions for use or other additional information materials dealing with the safety of those particular medical devices,
 - d) their employees and patients were informed about the need to review the proper condition, functioning and safe use of the medical device each time before it is used, if such review of that particular medical device and the way of its determined purpose of use is reasonable; this obligation applies to an adequate extent also to the accessories, software and any other object connected to the medical device.

(2) During the take-over of the medical device from the distribution phase providers are obliged to make sure that

- a) the medical device is equipped with instructions for use or other instructions related to its safe use and maintenance, including disinfection and sterilization of the medical device, all in the Czech language,
- b) the requirements on sterility are met together with any indications related to the instructions for use or other instructions preventing any intervention in packaging and ensuring safe sterilization, if the medical device is to be sterile,
- c) whoever sells a medical device is assured that the manufacturer or importer has issued a declaration of conformity; this provision shall not apply after entry into force of the agreement on accession of the Czech Republic to the European Union.

(3) In order to prevent unexpected risks the Ministry can determine by decree

- a) types of medical devices posing an increased risk to the user or third persons,
- b) types of medical devices which will be monitored after their placing on the market or which are to be listed in the register of implantable medical devices,
- c) other conditions of use of a medical device or types of medical devices exceeding the content of paragraph 1 and aimed at avoiding any harm to the health of the users and third persons,

- d) the way of establishment and management of the register of implantable medical devices and the related obligations to notify, the processing of data obtained in this way, accessibility of data and methods of protecting patients' personal data.

Article 21

Information for the user

(1) Instructions for use of the medical device and information for the user related to its safe use in the provision of health care, supplied together with the medical device, have to be available to the user at any time.

(2) The person responsible for the implantation of a medical device is obliged to provide the patient to whom the medical device was implanted or his/her legal representative with detailed information containing data that allows for the identification of the medical device, accessories included, and instructions concerning patient's safety and behavior, including the description of situations when the patient should see a physician and of environmental influences that the patient should not expose him/herself to at all or only if suitable preventive measures were implemented.

(3) If necessary in order to protect the health and safety of patients, the Ministry may determine by decree further details of the type, content, provided extent and accessibility of information specified in paragraphs 1 and 2.

(4) When informing a patient about the use of a medical device, the corresponding instructions for use of that medical device and information specified in paragraph 1 must be observed.

Article 22

Briefing

(1) Medical devices posing increased risk [Article 20(3) letter a) and b)] can only be used by individuals who

- a) were briefed about the corresponding medical device or a medical device of that type in accordance with the corresponding instructions for use,
- b) are acquainted with
 - 1. information specified in Article 21(1), and
 - 2. special risks related to the use of these specific medical devices.

(2) Briefing can only be performed by persons who are fit to brief others on the handling and use of medical devices on the grounds of their education, knowledge, practical experience and instruction from the producer. If necessary, the provider using these medical devices is obliged to organize repeated briefings according to a pre-established plan, in addition to briefings of new employees appointed to use or operate them.

(3) If medical devices specified in Article 20(3) letters a) and b) are used together with accessories, necessary software equipment or other medical devices, the briefing must also cover these combinations and their specific characteristics.

(4) Records of briefings stipulated for by paragraphs 1 and 2 must be kept and must be stored for the period of 5 years.

(5) It is the obligation of the producer or supplier to ensure that briefing is done by persons defined in paragraph 2.

Installation and use of medical devices

Article 23

(1) Medical devices must be installed in accordance with this Act, special legal regulations,^{20a)} generally accepted technical rules and regulations stipulating for the safety and health protection at work, and used in accordance with their determined purpose of use. These devices cannot be installed and used if they show deficiencies that might pose risk to human health.

(2) Having agreed with the Ministry of Industry and Trade, and in case of medical devices using nuclear energy and ionizing radiation also with the State Nuclear Safety Office, the Ministry may determine by decree the requirements concerning

- a) keeping of medical device operation logs,
- b) types and number of medical devices required to provide certain medical services,
- c) transfer of information obtained in relation to the use of these devices to the Ministry and the Institute of Healthcare Information and Statistics of the Czech Republic (hereinafter referred to as the “Statistical Institute”) for processing.

Article 24

(1) Having agreed with the Ministry of Industry and Trade, and in case of medical devices using nuclear energy and ionizing radiation also with the State Nuclear Safety Office, the Ministry can determine by decree

- a) the frequency, extent and method of technical revisions of measurement in medical devices with a measuring function which are subject to technical revisions of measurement,
- b) details related to the extent and method of authorization of persons who will perform technical revisions of measurement with respect to medical devices specified under letter a) and the method of inspecting their activity.

(2) With respect to medical devices with a measuring function which they are using in the provision of health care the providers are obliged to

^{20a)} For example Act No. 18/1997 Coll., on peaceful use of nuclear energy and ionizing radiation (the Atomic Act) and on amendment and supplements to some acts, as later amended, Act No. 22/1997 Coll., as later amended, Government Order No. 181/2001 Coll., as amended by Government Order No. 336/2001 Coll., Government Order No.191/2001 Coll., as amended by Government Order No. 337/2001 Coll.

- a) adopt measures that will guarantee sufficient precision and reliability of measurement, and
- b) duly cooperate in technical revisions of measurement.

Article 25

Cleaning, disinfection and sterilization of medical devices

(1) Instructions for use, information from the producer and technical requirements²¹⁾ must be taken into account during cleaning, disinfection and sterilization of medical devices with respect to the particular type of medical device. These activities shall be carried out by means of suitable equipment or equipment systems and suitable methods with respect to the type, size and extent of the provider's activity.

(2) The Ministry may determine by decree the requirements to be met and protocol to be followed by providers during cleaning, disinfection and sterilization of medical devices.

Article 26

cancelled

Article 27

Regular technical and safety revisions of medical devices

(1) To ensure the safety of users and third persons and proper condition of medical devices the Ministry can in accordance with the instructions for use and producers' instructions determine by decree

- a) the types or categories of medical devices which have to undergo regular revisions,
- b) basic requirements on the type, method, extent and frequency of regular revisions of medical devices.

(2) Providers are obliged to arrange for the revisions stipulated for by paragraph 1 and ensure that they are carried out by a qualified person in accordance with the provisions of Articles 28 and 29.

Article 28

Maintenance and servicing of medical devices

²¹⁾ Government Order No. 181/2001 Coll., as amended by Government Order No. 336/2001 Coll.
Government Order No. 191/2001 Coll., as amended by Government Order No. 337/2001 Coll.
Government Order No. 286/2001 Coll.

(1) Medical devices must be demonstrably and professionally maintained in due condition by means of revisions, care, adjustment, repair and testing performed in accordance with the producer's instructions, applicable special legal regulations^{22a)} and regulations stipulating for the operation of medical devices (hereinafter referred to as the "servicing") with the aim of meeting the requirement of Article 4(2) first sentence.

(2) The provider can carry out servicing only

- a) through employees whose professional training, experience, knowledge, knowledge of the relevant legal regulations and standards,^{22b)} and briefing in accordance with Article 22 (at least to the extent established by the instructions for use or operation)
1. correspond to the level of intervention in structural and functional components of the medical device, scope of the individual operations and their complexity,
 2. provide guarantees that activities listed in point 1 shall be executed professionally and shall not have a negative impact on the features (properties) of the medical device as determined by its producer,
 3. allow them in each individual case to assess and identify the measures necessary to recognize possible consequences and risks in terms of safety and functioning of the medical device,
 4. allow them to implement the necessary preventive measures, and
- b) if the provider possesses adequate material and technical equipment (premises and facilities, also with respect to their size, furnished and equipped with the necessary instruments, tools or other devices for work) to service the particular medical device.

(3) The provider can outsource servicing to another person who meets the conditions of paragraph 2 letters a) and b).

(4) The person appointed to carry out servicing or expert evaluation of the condition of a medical device performs these activities independently of other persons, who must not exert any influence on the appointed person.

(5) After completion of servicing which might have had a significant impact on the structural and functional components of the medical device the safety and functioning of this device must be tested.

(6) The person carrying out servicing is obliged to provide the Institute with the required documents and true information within a period of time determined by the Institute and facilitate their verification, including access to premises or equipment that the person is using to service the medical devices.

(7) Revision, care and the related testing of medical devices can be performed by individuals specified in paragraph 2 letter a); if the provider appoints a legal person to perform these activities, this person is responsible for the fact that its employees charged with the revision and assessment of the professional condition of medical devices meet this requirement.

^{22a)} For example Act No. 174/1968 Coll., on expert state surveillance over safety at work, as later amended, Act No. 18/1997 Coll., as later amended, Act No. 79/1997 Coll., as later amended, and Decree No. 50/1978 Coll., on professional qualification in electrotechnics, as amended by Decree No. 98/1982 Coll.

^{22b)} Article 4 and 4a of Act No. 22/1997 Coll., as later amended.

(8) In case of medical devices using nuclear energy or ionizing radiation the Ministry can determine by decree and in agreement with the Ministry of Industry and Trade and the State Nuclear Safety Office

- a) further details of requirements specified in paragraphs 2 and 7,
- b) the protocol of verification of qualifications of persons specified in paragraphs 2 and 7,
- c) requirements on servicing specified in paragraph 2 letter b),
- d) the protocol of inspection of persons who carry out servicing.

Article 29

Special provisions regulating operation

In order to ensure safety and protection of health of the users and third persons and with respect to the required quality, safety and effectiveness of medical devices the Ministry can in agreement with the Ministry of Industry and Trade determine by decree

- a) measures to enhance the effectiveness of information and consultancy activities specified in Articles 21 a 22,
- b) requirements concerning
 1. premises, or also facilities, used by the distributor, especially with respect to their quality, size and equipment,
 2. hygiene and sanitation (hygiene and sanitation rules) in the area of production, import, distribution, use and servicing of medical devices,
 3. maintenance of medical devices at provider's facilities,
 4. keeping of records and storage of documents related to operating procedures in production, import, distribution, use in the provision of health care, maintenance and servicing of medical devices,
 5. guarantees of consistency and accuracy of measuring devices which are medical devices and the qualification of employees with respect to the fulfillment of metrological requirements concerning medical devices,^{22c)}
 6. types and labeling of containers and packaging, especially those used for storing medical devices,
 7. labeling, removal from operation and liquidation of medical devices unfit for use.

Article 30

Registration of medical devices

(1) Providers are obliged to keep a register of medical devices

- a) specified in Article 20(3) letters a) and b),
- b) subject to obligatory regular revisions,
- c) of investment nature; this register must allow for an immediate identification of the location of these devices,
- d) related to information and consultancy activities specified in Articles 21 a 22.

^{22c)} Act No. 505/1990 Coll., on metrology, as later amended.

(2) The execution of revisions specified in paragraph 1 letter b) and testing of medical devices after servicing, including the results of such revisions and testing, must be documented.

(3) If the provider's facility contains a radiological unit, the provider is obliged to keep, in addition to registers of medical devices stipulated for by paragraph 1, an inventory of radiological equipment.

Title VI **OBLIGATION TO NOTIFY**

Article 31

Obligations to report

(1) Producers, importers and distributors of medical devices or other persons placing a medical device on the market for the first time have the obligation to report to the Ministry all information determined by Government Order. This report can only be made once the conformity of the medical devices was assessed with respect to their determined purpose of use, they are duly labeled,^{7a)} the producer or the importer issued the declaration of conformity and the devices are ready to be placed on the market.

(2) Persons who assemble the sets and systems of medical devices in order to place them on the market in that form or who sterilize them or sterilize other medical devices bearing the conformity marking^{7a)} which the producer expects to be sterilized before use in order to be placed on the market for the first time are obliged to report to the Ministry before starting their activities

- a) the name, surname, permanent residence and place of business or address of business premises in case of physical persons; the company name or brand, seat and address of business premises in case of legal persons,
- b) type and scope of the performed activity and the date of its start,
- c) data enabling identification of the corresponding set or system of medical devices (description), and
- d) date of sterilization of the set or system of medical devices, including the period of its effectiveness.

The required information is reported on forms established by a Government Order.

(3) Persons carrying out servicing (Article 28) are obliged to report to the Ministry

- a) the name, surname, permanent residence and place of business or address of the business premises in case of physical persons; the company name or brand, seat and address of the business premises in case of legal persons,
- b) type and scope of the performed activity and the date of its start,
- c) data of the license, on the basis of which the activity is performed.

The required information is reported on forms determined by a Government Order.

(4) Persons listed in paragraphs 1 to 3 have to inform the Ministry about any change in data specified in the same paragraphs within 30 days of the day when the change occurred.

(5) The Ministry evaluates the data obtained on the basis of the above provisions and of Article 32(3) and as applicable determines, coordinates and reviews measures that must be implemented according to this Act. This does not affect the liability of persons who place medical devices on the market and put into service and use them to provide health care.

Notification, registration, investigation and prevention of adverse events

Article 32

(1) Producers, importers, distributors, providers, authorized bodies,²³⁾ accredited persons²⁴⁾ or persons carrying out the servicing are obliged to report to the Institute in writing all adverse events they identified or were informed about.

(2) In case of risk due to delay, employees of the persons listed in paragraph 1 are also authorized to report to the Institute any adverse event related to the death of an individual if they identify it or are informed about it and the statutory person of the persons listed in paragraph 1 cannot be reached.

(3) When the Institute identifies or is informed about an adverse event, it shall without delay

- a) notify about this fact
 1. the producer or importer of the corresponding medical device,
 2. the Ministry, indicating the adopted measures, and
 3. the Police of the Czech Republic in case of a suspected criminal act,
- b) start the investigation,
- c) implement adequate measures to mitigate its eventual harmful effects and to prevent its repetition.

(4) The report stipulated for by paragraph 1 shall contain

- a) the name, surname, permanent residence and place of business operations or address of the premises if the report is made by a physical person; company name or brand, seat and address of the premises if the report is made by a legal person,
- b) description of the medical device drafted as stipulated for by a special legal regulation,²⁵⁾
- c) company name (brand), seat of the authorized body and its identification number if this person was involved in the assessment of conformity of the medical device during the use of which the adverse event occurred,
- d) description of the adverse event, time and place of its occurrence, who discovered it, and its cause if known, and
- e) the adopted measures.

(5) The Institute

- a) informs the Ministry and if necessary also the Commission of the European Communities about the findings of investigation of the adverse event,

²³⁾ Article 11(1) of Act No. 22/1997 Coll., as amended by Act No. 71/2000 Coll.

²⁴⁾ Article 14(1) of Act No. 22/1997 Coll., as amended by Act No. 71/2000 Coll.

²⁵⁾ Annex No. 1 to Government Order No. 181/2001 Coll.

Annex No. 1 to Government Order No. 191/2001 Coll.

Annex No. 1 to Government Order No. 286/2001 Coll.

- b) publishes in the Bulletin of the State Drug Control Institute information about adverse events in which causal relationship between the event and the use of a particular medical device in the provision of health care was proved.

Article 33

(1) Providers in whose facilities an adverse event resulting in a patient's death or in damage to the health of a patient occurred are obliged to record this fact in the medical history of the aggrieved patient.

(2) The Institute keeps records of adverse events identified according to Article 32(1) and 2, keeps and stores records of their investigation for a period of at least 15 years; in case of adverse events resulting in damage to health or death of an individual the Institute stores the records of their investigation for the period of 30 years.

Article 34

The Ministry shall determine by decree the forms, methods of reporting of adverse events, their registration, investigation, evaluation, documentation including storage of documents, and subsequent monitoring aimed at preventing the occurrence of adverse events and especially their repetition.

Article 35

In relation to the evaluation of the content of notifications according to Article 32 and reasonable suspicions according to Article 4(4) letter a) which became known to them in the course of performance of their activities in the area of medical devices, the providers are obliged to

- a) according to their powers implement the necessary measures facilitating early identification and evaluation of possible risks and threats to the health and safety of the users and third persons, aimed at preventing adverse consequences,
- b) support investigation of adverse events and protective measures against the risks by all available means and if necessary carry out their own investigation of medical devices or arrange for such investigation and make its results available to the corresponding administrative bodies without delay,
- c) ensure access to
 1. medical devices and their instructions for use or any additional information about them, and
 2. the assurance that the conformity of the medical device was assessed,
- d) if necessary facilitate the comparison of medical devices with other medical devices of the same or similar type in their possession,
- e) provide
 1. information to clarify and assess the specific conditions of installation, use and maintenance of medical devices, and
 2. data obtained from monitoring of medical devices posing increased risk to users or third persons [Article 20(3) letters a) and b)], and

- f) inform the Ministry without delay about cases specified in Article 4(4) letters a) and c).

Title VII
MEASURES TO ENSURE SAFETY OF MEDICAL DEVICES

Article 36

Medical device safety plan

In order to ensure safety of medical devices and prevention of adverse events and their consequences and to fulfill the tasks arising from this Act the Ministry may establish by decree and in agreement with the Ministry of Industry and Trade a safety plan for medical devices, which shall comprise especially

- a) a sustained and coordinated synergy of producers, importers, distributors and sellers of medical devices and persons performing servicing activities, their cooperation with the public administration bodies, professional chambers, experts and corresponding international bodies and organizations,
- b) blueprint protocols to be followed by the public administration bodies, producers, importers, distributors, sellers of medical devices, persons performing servicing activities and providers in case of occurrence or envisaged occurrence of an adverse event,
- c) means of communication, system of the sharing of data obtained from obligatory notifications, protocol of its use and of the coverage of related costs,
- d) protocol of data storage.

Title VIII
**EXECUTION OF PUBLIC ADMINISTRATION AND OTHER ACTIVITIES
IN THE AREA OF MEDICAL DEVICES**

Article 37

Public administration bodies

Public administration in the area of medical devices designed for use in the provision of health care is executed by

- a) the Ministry,
- b) the Ministry of Interior, Ministry of Justice, and Ministry of Defense (hereinafter referred to as the “relevant ministries”), and
- c) the Institute.

Article 38

Ministry

In the area of medical devices the Ministry

- a) fulfills
 1. tasks arising from this Act and from special legal regulations,³⁾

2. the function of the supreme body of the Czech Republic to the extent determined by this Act and special legal regulations³⁾ or international agreements,
- b) fulfills the tasks specified in Article 41(1) and 3 through the Statistical Institute,
- c) defines the concept of the provision of health care with medical devices,
- d) reviews
1. activity of the Institute carried out in accordance with Article 40,
 2. completeness of information delivered to the Ministry in fulfillment of the obligations to notify arising for the subjects from this Act and other special legal regulations,³⁾
 3. compliance with a special legal regulation,²⁶⁾
- e) continually evaluates information obtained in accordance with letter d) point 2 and letter f) and the adopted measures and on the basis of them adopts adequate new measures; passes comprehensive data on to the Statistical Institute for statistical processing, registration and further use for outputs determined by the Ministry,
- f) evaluates measures adopted by the Institute and issues statements concerning measures adopted by the authorized bodies or producers and importers, if they informed the Ministry that
1. in the course of their activity they identified facts which can in their consequences pose a risk to the life or health of individuals, or
 2. an adverse event occurred during the use of medical devices which were used in compliance with the way and conditions envisaged by this Act or special legal regulations,²¹⁾
- g) coordinates measures
1. to prevent side effects of medical devices and of their combinations with other substances or products,
 2. to prevent forgery, functional defects and technical deficiencies in medical devices,
- h) ensures
1. the conditions for fulfillment of tasks in its area of competence in the execution of this Act and its implementation regulations,
 2. international cooperation in the area of medical devices, including the fulfillment of tasks arising for the Czech Republic from international agreements,
- i) charges the providers with accommodation of performance of clinical evaluation and clinical testing,
- j) performs
1. coordination of clinical testing if necessary, and ensures other related measures,
 2. information, consultancy, educational and publishing activities,
- k) reviews the rulings of the Institute issued in administrative proceedings,
- l) provides guidance in the activity of
1. the Statistical Institute,
 2. the Institute,
- m) cooperates
1. with the relevant bodies of foreign states and the Commission of the European Communities, World Health Organization, bodies responsible for the safety and protection of health at work, the State Nuclear Safety Office, the Office, the Czech Accreditation Institute, the Czech Metrology Institute, Czech Standards Institute, associations of producers and importers of medical devices, and the authorized bodies,²³⁾ or accredited persons,²⁴⁾ experts,²⁷⁾ distributors, sectoral legal persons and other entities who within the scope of their activity register the risks related to medical

²⁶⁾ Act No. 40/1995 Coll., on the regulation of advertising and on amendment to Act No. 468/1991 Coll., on television and radio broadcasting, as later amended.

²⁷⁾ Act No. 36/1967 Coll., on experts and interpreters.

- devices, in order to ensure sustained safety, suitability and effectiveness of medical devices,
2. with the Office in providing conformity assessment in case of medical devices requiring obligatory involvement of an authorized body,
 3. with the State Nuclear Safety Office for the purpose of regulation of the number of devices in case of an undesirable increase in their number,
- ~~n) issues statements with respect to authorization according to a special legal regulation,⁸⁾ with respect to concession applications according to Article 18,~~
- n) gives opinion to the issuing of authorization pursuant to a special legal regulation,⁸⁾
- o) establishes an Ethical Commission for the purpose of clinical testing with the Ministry and registers Ethical Commissions established with the providers,
 - p) grants exceptions in accordance with Article 7(1),
 - q) informs the Institute about clinical testing.

Article 39

Relevant Ministries

- In their respective areas of competence the relevant Ministries
- a) procure medical devices for their structural units; they are not subject to reporting according to Article 31 as long as they do not place medical devices on the market,
 - b) review compliance with this Act and other special legal regulations³⁾ in accordance with the provisions of Articles 43 and 44; in case of their breach proceed as stipulated for by special legal regulations,
 - c) inform the Ministry about the cases specified in Article 4(4) letters a) and c),
 - d) grant exceptions in accordance with Article 7(1).

Article 40

Institute

(1) The Institute is an administration authority²⁸⁾ also for the purpose of performance of activities specified in paragraph 2.

(2) In the area of medical devices the Institute

- a) inspects the providers to review
 1. execution of preventive revisions, maintenance and repair of medical devices, verification of the accuracy of measurement, technical condition and observance of the determined purpose of use of these medical devices,
 2. keeping and storage of registers and documentation concerning medical devices, instructions for use of these devices and records of employee briefings according to Article 22, regular revisions of medical devices and adverse events,

⁸⁾ Article 11 of Act No. 22/1997 Coll., as amended by Act No. 71/2000 Coll.

²⁸⁾ Article 67 of Act No. 79/1997 Coll.

3. use of medical devices in terms of fulfillment of requirements arising from the instructions for use and information (Article 21),
 4. execution of clinical evaluation and clinical testing, if necessary the Institute implements adequate measures (including discontinuation); the Institute informs the Ministry and the ordering party about the adopted measures without delay,
 5. conditions to be met by the workplace where clinical evaluation or clinical testing of medical devices will take place (Article 15(2)),
 6. fulfillment of obligations related to the operation of medical devices according to Article 29,
- b) imposes on the inspected persons by its ruling
1. the duty to eliminate all identified deficiencies and defines the deadline of their elimination,
 2. protective measures, namely the suspension or termination of the use of a medical device in the provision of healthcare if a direct risk of damage to the health of individuals is related to it; an appeal filed against this ruling does not defer its effect; the cost of its fulfillment is born by the person who uses the medical device in the provision of health care,
 3. fines for infringements of this Act according to Article 46;
 4. the Institute informs the Ministry about these rulings without delay,
- c) carries out investigation of adverse events and if necessary implements adequate measures in due time. The Institute submits the assessment of adverse events to the Ministry and cooperates in this area with the corresponding bodies of the Commission of the European Communities and foreign states,
- d) informs the Ministry without delay and proposes measures in case of identification of
1. increased risks to users and third persons related to the use of a medical device,
 2. a medical device wrongfully bearing the conformity label,
 3. a fact casting doubt on the assessment of a product, on the decision whether it is or it is not a medical device, and its classification; the cost of expert opinion is born by the person who erred in its decision,
 4. cases specified in Article 4(4) letters a) and c).

Article 41

Statistical Institute

(1) The Statistical Institute

- a) establishes and maintains central registers in the area of medical devices and information system related to medical devices,
- b) implements measures to protect data collected in accordance with Articles 31, 32 and 35, and
- c) provides information from it to persons who prove legal interest.

(2) The content and scope of data accumulated in the central register and the information system, the method of use and communication of data in accordance with paragraph 1, as well as the range of persons authorized to have access to central registers in the area of medical devices and the information system shall be determined by the Ministry for the Statistical Institute.

(3) The Statistical Institute also

- a) keeps and centrally processes data obtained
 - 1. in accordance with Articles 31, 32 and 35,
 - 2. through monitoring, collection, evaluation and assessment of risks related to medical devices,
 - 3. from therelevant administration authorities,
- b) provides information
 - 1. in accordance with paragraph 1,
 - 2. to competent bodies of foreign states and the Commission of the European Communities, especially with respect to risks related to the use of medical devices in the provision of health care and protection against these risks,
- c) implements adequate measures to ensure that only persons specified in paragraph 2 have access to data from the information system.

Title IX **INSPECTION**

Article 42

Object and scope of inspection in the area of use of medical devices

(1) Inspection applies to medical devices, facilities and persons who in the Czech Republic

- a) use these medical devices in the provision of health care,
- b) perform clinical evaluation or clinical testing of these devices,
- c) fulfill tasks arising from Articles 29 and 30,
- d) prescribe these devices.

(2) Inspection is carried out through their employees charged with this activity (hereinafter referred to as the “inspectors”), by

- a) the Ministry,²⁹⁾
- b) the Institute to the extent specified in Article 40(2) letter a) and according to paragraph 3,
- c) the relevant ministries.

(3) Within the framework of investigation of an adverse event the inspectors of the Institute also inspect medical devices and the related documentation of the producer, importer, distributor and the person providing maintenance and servicing of the medical device. The Institute informs the Czech Trade Inspection about its intention to carry out inspection according to the previous sentence.

Article 43

Inspectors’ rights and obligations

(1) Inspection can only be carried out by an inspector who

²⁹⁾ Article 7 letter b) of Act No. 40/1995 Coll.

- a) is not biased with respect to persons specified in Article 42(1) and (3) (hereinafter referred to as “the inspected persons”) or to the object of inspection,
- b) has the necessary organizational strengths to ensure proper execution of the inspection and its reproducibility,
- c) has the necessary professional qualification, especially adequate education, experience and expert knowledge, including knowledge of the relevant legal regulations and standards,
- d) has the necessary measurement and control devices at his/her disposal.

(2) During the inspection the inspector has the right to

- a) access the land, premises, facilities and rooms of the inspected person if they are related to the object of inspection,
- b) demand explanation of the findings as well as the submission of letters, documents and data records on computer technology storage media related to the object of inspection by the determined deadlines,
- c) examine the documentation, designs, production, assessment of conformity and execution of clinical evaluation or clinical testing of a medical device if investigating an adverse event,
- d) produce
 1. copies of letters and documents specified in letter b) and excerpts of these; if this cannot be done, these letters and documents can be appropriated if it is indispensable for the performance of inspection; if the reasons for the inspection cease to exist the inspector is obliged to return the appropriated documents,
 2. visual documentation related to the inspection,
- e) collect samples of medical devices, their parts or components to the extent absolutely indispensable for performing the inspection,
- f) demand execution of the corresponding tests of a medical device which the inspected person has at its disposal or which was handed over by the inspector as part of the performed inspection,
- g) demand handover of letters and documents related to the advertising of the medical device and demand explanation of findings,
- h) use telecommunication equipment of the inspected person if its use is indispensable to secure inspection,
- i) involve other persons in the inspection against payment if it is necessary for the evaluation of expert issues related to the execution of the inspection; these persons are bound by the confidentiality clause according to Article 49. The price of services of the authorized bodies is determined in accordance with a special legal regulation,³⁰⁾ if not stated otherwise in this Act.

(3) The inspector is obliged to

- a) inform the inspected person about the start of inspection and present a written authorization to perform it,
- b) discuss the identified deficiencies and the method and deadline of their elimination with the inspected person,
- c) produce a record of the progress and results of the inspection and hand a copy over to the inspected person while informing it about the means of redress,

³⁰⁾ Article 1(2) letter a) of Act No. 526/1990 Coll., on prices, as later amended.

- d) observe the rights and legally protected interests of the inspected persons, and
- e) ensure due protection of the appropriated original documents against loss, destruction, damage or misuse.

Article 44

Inspected person

The inspected person is obliged to

- a) submit itself to inspection and duly cooperate with the inspector or persons involved by the inspector in an inspection that is in line with inspector's rights specified in Article 43(2) letters a) to g) and i), or
- b) facilitate for the inspector
 1. access to medical devices, or
 2. execution of tests, making its employees available for them, together with instruments required for this purpose.

Article 45

Inspection-related costs

(1) The costs incurred during inspection by the body executing the inspection in accordance with this Act shall be borne by the inspected person if

- a) the inspection was performed at this person's request; the amount to be paid is determined according to a special legal regulation,³¹⁾
- b) the medical device does not meet the requirements determined in accordance with special legal regulations.³⁾

(2) The inspected person shall be reimbursed for the cost of the collected samples at the amount of the price at which the medical device, its part or component are being offered at the moment of collection. Reimbursement shall not be paid if the inspected person waives it, and the inspected person is not entitled to receive reimbursement if the medical device, its part or component do not meet the requirements determined by this Act and special legal regulations.³⁾

Title X **FINES**

Imposition of fines

Article 46

³¹⁾ Act No. 526/1990 Coll., as later amended.

(1) The Institute shall impose on the person in breach of or failing to meet its obligations determined by this Act a fine of

- a) up to 1 000 000 CZK on the person in breach of obligations specified in Article 11(3),
- b) up to 600 000 CZK to those in breach of obligations specified in Article 4(1) and (2), Article 8(1) and Article 14(2) letter a),
- c) up to 300 000 CZK to those who
 - 1. used a medical device in the provision of health care differently than for its determined purpose of use,
 - 2. breached their obligation specified in Article 49,
- d) up to 200 000 CZK to those in breach of obligations specified in Article 4(3) to 5, Article 10, Article 11(1), (2), (4) to (6), Article 13, Article 14(1), Article 14(2) letters b) to g) and Article 14(3), Article 19, Article 20(1) and (2), Article 21(1) and (2), Article 22(1) to (3) and (5), Article 23(1), Article 24(2), Article 28(2) and (5), Article 32(1) and (4), Article 44 and Article 52(2) ~~and~~ to (6),
- e) up to 100 000 CZK to those in breach of obligations specified in Article 6(2), Article 12, Article 17(1), Article 22(4), Article 25(1), Article 27(2), Article 28(1), (3) and (4), Article 30, Article 31(1) to (4), Article 33(1) and Article 35.

(2) A fine at double the amount may be imposed for a repeated breach of obligations specified in paragraph 1.

(3) The fine is payable within 30 days of the day of effectiveness of the decision about its imposition; fines are collected and enforced by the Institute.

(4) The fines are a state budget income.

(5) The imposition of a fine does not affect the obligation to pay damages.³²⁾

Article 47

(1) If a fine was imposed according to this Act, no fines according to other legal regulations³³⁾ may be imposed for the same breach of obligation.

(2) The fine may be imposed no later than within one year of the day when the body authorized to impose the fine became aware of the breach of obligation determined by this Act, however, no later than within 5 years of the day when the breach of such obligation occurred.

(3) The gravity of the breach of the statutory obligations, the extent of the actual or possible damage to the health of individuals, and the circumstances of the wrongful behavior shall be taken into consideration when a fine is being imposed.

³²⁾ Act No. 59/1998 Coll., on the responsibility for damage caused by faulty product.

³³⁾ For example according to Article 19 of Act No. 22/1997 Coll., as amended by Act No. 71/2000 Coll.

Title XI
COMMON, TEMPORARY AND FINAL PROVISIONS

Article 48

Application of administrative procedure regulations

The decisions according to [Article 4\(5\)](#), Article 15(1), Article 16(2), Article 38 letter k) and Article 40(2) letter b) are regulated by a special legal regulation.³⁴⁾

Article 49

Confidentiality

(1) Persons providing and executing clinical evaluation or clinical testing of medical devices, members of the relevant Ethical Commission, persons providing and executing investigation of adverse events, inspectors carrying out inspection activities according to this Act and the relevant employees of the Institute, Statistical Institute and the Ministry are obliged to respect the confidentiality of facts that became known to them in the course of fulfillment of their tasks arising from this Act.

(2) The obligation specified in paragraph 1 does not apply to the content and indispensable scope of information in cases

- a) of criminal proceedings according to special legal regulations,³⁵⁾
- b) arising from
 1. the obligations to notify stipulated for by this Act, and
 2. international commitments by which the Czech Republic is bound,except for the personal data of physical persons.

Article 50

Cost

(1) The providers of expert services provided upon request in accordance with this Act and other special legal regulations^{7a)} may ask to be reimbursed for the cost of these services.

³⁴⁾ Act No. 71/1967 Coll., on administrative proceedings (rules of administration procedure), as amended by Act No. 29/2000 Coll.

³⁵⁾ Act No. 140/1961 Coll., penal law, as later amended.
Act No. 141/1961 Coll., on criminal proceedings (criminal procedure), as later amended.

- (2) The providers of services according to paragraph 1
- a) are entitled to demand from the person upon whose request such services are to be provided an adequate advance payment or even a prior settlement of cost if it is obvious that the services will be provided and if their approximate cost is known,
 - b) can waive the reimbursement of cost if the services are to be provided in public interest or may have especially significant consequences for a larger group of persons.
- (3) The reimbursement may also be demanded for unfinished services if the person who orders them duly justifies them.

Article 51

(1) Wherever the term “technical healthcare device” is used in other regulations, it is understood to mean a “medical device”.

(2) Wherever the term “subject of evaluation” is used in other regulations, it is replaced by the term “subjects”.

Article 52

Temporary provision

(1) The license for the use of a medical device in the provision of health care issued by the Ministry or the Institute is valid during the period of time specified on this license; if no period of time is specified, the medical device can be used in the provision of health care until 31 December 2005. The periods mentioned in the previous sentence can be extended by the Ministry upon provider’s request submitted at least 6 months before the expiry of the license period and this extension can be granted even repeatedly; the provider shall attach the results of assessment of fulfillment of the medical and technical requirements determined for the medical device by the producer to the application for license extension. The fulfillment of technical requirements shall be assessed by duly accredited legal persons;⁹⁾ the fulfillment of medical requirements shall be assessed by legal persons appointed by the Ministry in accordance with Article 38 letter i); the Ministry keeps a listing of such persons.

(2) The license for the use of a medical device in the provision of health care issued by the Ministry or the Institute in accordance with Article 62(3) of Act No. 20/1966 Coll., on care for the health of the nation, as amended by Act No. 548/1991 Coll., is considered to be the proof of suitability of the medical device according to Article 8. This document is valid during the period of time specified on it; if no period of time is specified, the medical device can be used in the provision of health care until 31 December 2005.

(3) Except for medical devices of class III and IIb, medical devices that do not meet the provision of paragraph 2, the conformity of which was not assessed through procedures stipulated for by special legal regulations, and which were put into service before 31 December 1999, may be used in the provision of health care only in accordance with their determined purpose of use and in accordance with the provision of Article 28, as long as their date of expiry has not passed yet, providing that it was specified by the producer.

⁹⁾ Article 14 of Act No. 22/1997 Coll., as amended by Act No. 71/2000 Coll.

(4) Medical devices of class III and IIb that do not meet the provision of paragraph 2 may be used in the provision of health care only if the provider uses them in accordance with their determined purpose of use and with the provision of Article 28, as long as their date of expiry has not passed yet, providing that it was specified by the producer, and if the provider ensures their condition to be tested by the deadlines specified in paragraph 6 and proves that the level of performance (properties) of the tested device complies with the technical regulations or technical documents or technical standards^{7e)} according to which it was produced, and shall prove it by means of records made by persons

- a) registered in accordance with Article 31, who meet the conditions of Article 28(2) for this medical device, or
- b) who have the corresponding accreditation for this activity.⁹⁾

In case of medical devices using nuclear energy or ionizing radiation the provider shall prove that the requirements on protection against radiation stipulated for by a special legal regulation³⁶⁾ were met in this medical device; in case of medical devices with a measuring function the provider shall prove the level of their metrological performance (properties) by means of records of testing prescribed by the producer or an accredited person and by means of documents stipulated for by special legal regulations.^{22c)}

(5) Reports and records specified in paragraph 4 must contain

- a) verbal evaluation of the condition of the medical device and a statement specifying whether the medical device meets the conditions of paragraph 4; if the medical device does not meet the conditions of paragraph 4, the corresponding report or record must also indicate the reasons for such conclusion, and
- b) the date of the next test of condition of the medical device according to paragraph 4.

The classification of medical devices subject to provisions of paragraphs 3 and 4 according to rules determined by a special legal regulation^{9a)} is the responsibility of the provider.

(6) Medical devices put into service

- a) before 1 January 1991 must be tested before 31 December 2004,
- b) from 1 January 1991 to 31 December 1999 must be tested before 31 December 2005.

PART TWO

Amendment to Act on Trading Activities

/Note: this means Act No.455/1991 Coll., on Trading Activities (Trading Act), as later amended/

PART THREE

Amendment to Act on Public Health Protection

/Note: this means Act No.20/1966 Coll., on Public Health Protection, as later amended/

The text of PARTS TWO and THREE is not reproduced.

³⁶⁾ Act No. 18/1997 Coll., as later amended

PART FOUR
EFFECTIVENESS

Article 58

This Act becomes effective as of the first day of the second month following the day of its promulgation.

/Note: Act No.123/2000 Coll. became effective as of 1 July 2000/

* * *

Act No. 130/2003 Coll., amending Act No. 123/2000 Coll., on medical devices was promulgated on 6 May 2003 and became effective on 1 September 2003 with the exception of Article 3 letter l), Article 4(6), Article 8(1) letter b) and Article 11(5) letter b) which were to become effective on the day of entry into effect of the agreement on accession of the Czech Republic to the European Union; on the same day Article 4(4) letter d) will cease to be effective.

* * *

Act No.274/2003 Coll., amending Act No.123/2000 Coll., as amended, was promulgated with effectiveness as of 1 October 2003 with the exception of Article 8(1) letter b) to become effective on the date of publication of Sectoral Annex “Medical Devices” to the Protocol to the Europe Agreement establishing an association between the Czech Republic, of the one part, and the European Communities and their Member States, of the other part, on Conformity Assessment and Acceptance of Industrial Products in the Collection of International Agreements or on the day of coming into effect of the agreement on accession of the Czech Republic to the European Union, whichever date will come first.