375/2022 Coll.

ACT

of 3 November 2022

on medical devices and on in vitro diagnostic medical devices

The Parliament has passed this Act of the Czech Republic:

PART ONE

INTRODUCTORY PROVISIONS

Section 1

Subject matter

Further to Regulation (EU) 2017/745 of the European Parliament and of the Council[1)] (hereinafter referred to as the "Medical Device Regulation") and Regulation (EU) 2017/746 of the European Parliament and of the Council[2)] (hereinafter referred to as the "In Vitro Diagnostic Medical Device Regulation"), this Act:

a) stipulates the powers of administrative authorities in their performance of state administration in the sphere of medical devices and in vitro diagnostic medical devices;

b) complements the rules stipulated by the Medical Device Regulation, by the In Vitro Diagnostic Medical Device Regulation or by directly applicable regulations of the European Union adopted on the basis of the former;

c) specifies the Medical Device Information System;

d) sets forth the prescribing and dispensing of medical devices and in vitro diagnostic medical devices, their use, and the conditions of their servicing.

Section 2

Medical device, in vitro diagnostic medical device, and device

(1) For the purposes of this Act, a medical device shall mean a medical device as defined by Art. 2(1) of the Medical Device Regulation, accessory for a medical device as defined by Art. 2(2) of the Medical Device Regulation, and a product referred to under Annex XVI to the Medical Device Regulation.

(2) For the purposes of this Act, an in vitro diagnostic medical device shall mean an in vitro diagnostic medical device as defined by Art. 2(2) of the In Vitro Diagnostic Medical Device Regulation or its accessory as defined by Art. 2(4) of the In Vitro Diagnostic Medical Device Regulation.

(3) For the purposes of this Act, a device shall mean a medical device and an in vitro diagnostic medical device.

PART TWO

PERFORMANCE OF STATE ADMINISTRATION

Section 3

State administration authorities

State administration in the sphere of devices is performed by:

a) the Ministry of Health (hereinafter referred to as the "Ministry");

b) the State Institute for Drug Control (hereinafter referred to as the "Institute");

c) the Office for Standards, Metrology and Testing.
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Section 4

Ministry

In the sphere of devices, the Ministry shall:

a) cooperate with relevant authorities of the European Union Member States and other states that are parties to the Agreement on the European Economic Area (hereinafter referred to as the "Member State") and represent the Czech Republic in working groups and committees of the European Union;

b) appoint representatives of the Czech Republic to the Medical Device Coordination Group and its subgroups in compliance with Article 103 of the Medical Device Regulation and Article 98 of the In Vitro Diagnostic Medical Device Regulation;

c) decide on granting exemptions referred to under Section 65(1);

d) repeal measures of the Institute found ill-founded by the European Commission (hereinafter referred to as the "Commission") as per Article 96 or 98 of the Medical Device Regulation or Article 91 or 93 of the In Vitro Diagnostic Medical Device Regulation;

e) cooperate with other administrative authorities and notified bodies.

Institute

Section 5

(1) The Institute shall execute the powers conferred by the Medical Device Regulation or by the In Vitro Diagnostic Medical Device Regulation or by directly applicable regulations of the European Union adopted on the basis of the former onto the Member State or its national competent authority, unles stipulated otherwise herein and unless it is a power within the sphere of notified bodies as per Articles 35 to 58 of the Medical Device Regulation or Articles 31 to 53 of the In Vitro Diagnostic Medical Device Regulation, the performance of which has been delegated by another legal regulation[3)] to the Office for Standards, Metrology and Testing.

(2) Furthermore, in the sphere of devices, the Institute shall, in particular:

a) represent, within the scope of its powers, the Czech Republic in working groups and committees of the European Union;

b) cooperate, within the scope of its powers, with the Office for Standards, Metrology and Testing and with the competent authorities of foreign countries, Member States, and the European Union;

c) receive notifications from manufacturers of custom-made devices, distributors, and persons

servicing devices;

d) establish, administer, and operate the Medical Device Information System;

e) decide on:
1. restricting and suspending the making available of a device on the market;
2. actions referred to under Art. 95(1) and Art. 98(1) of the Medical Device Regulation or Art. 90(1) and Art. 93(1) of the In Vitro Diagnostic Medical Device Regulation;
3. measures referred to by Commission implementing regulation as per Art. 59(3) and Art. 96(3) and Art. 98(4) of the Medical Device Regulation or Art. 54(3) and Art. 91(3) and Art. 93(4) of the In Vitro Diagnostic Medical Device Regulation;
4. device withdrawal from the market;
5. device recall;
6. restricting or terminating the use of a device;

f) decide whether a product is governed by the Medical Device Regulation or by the In Vitro Diagnostic Medical Device Regulation;

g) decide on granting exemptions referred to under Section 65(2);

h) perform market surveillance pursuant to the Medical Device Regulation or the In Vitro Diagnostic Medical Device Regulation, this Act, and the act governing conformity assessment of specified products when made available on the market[4)];

i) check compliance with this Act, the Medical Device Regulation, the In Vitro Diagnostic Medical Device Regulation, and directly applicable regulations of the European Union adopted on the basis of the Medical Device Regulation or the In Vitro Diagnostic Medical Device Regulation;

j) issue certificates of free sale;

k) adopt first-instance decisions on offences referred to under this Act;

l) conduct educational activities;

m) prepare expert opinions and provide expert consultations upon request;

n) adopt measures referred to under Art. 87(10) of the Medical Device Regulation or Art. 82(10) of the In Vitro Diagnostic Medical Device Regulation;

o) keep and publish a list of ethics committees established by healthcare provider and notified to the Institute pursuant to Section 13(1);

p) submit requests referred to under Art. 4(1) of the Medical Device Regulation or under Art. 3(1) of the In Vitro Diagnostic Medical Device Regulation;

q) issue measures referred to under Section 6(3);

r) establish, administer, and operate a central repository of electronic orders as part of the electronic prescription information system pursuant to the Act on Pharmaceuticals (hereinafter referred to as "ePrescription system");

s) publish on its website a list of dispensing persons with access to the ePrescription system for the purposes of dispensing of devices prescribed on order pursuant to Section 28(1)(a).

(3) Furthermore, in compliance with Art. 6(4) of the Medical Device Regulation or Art. 6(4) of the In Vitro Diagnostic Medical Device Regulation, the Institute, in order to protect public health, may require an information society service provider to stop the conduct of their activity due to a breach of fulfilment of obligations implied by the Medical Device Regulation or by the In Vitro Diagnostic Medical Device Regulation. Should the information society service provider fail to stop the conduct of their activity no later than within 30 days of the delivery of the request referred to in sentence one, the

Institute shall issue a decision by means of which it shall prohibit the information society service provider to conduct the activity in question. The Institute shall prohibit the conduct of activities only in such a scope within which the fulfilment of obligations implied by the Medical Device Regulation or by the In Vitro Diagnostic Medical Device Regulation is being breached. The Institute's decision is the first step in the procedure and any appeal therefrom shall have no suspensory effect. Documents in the procedure shall be delivered by means of a public notice; along with the posting of the public notice, the Institute shall send the document for the information society service provider to take note of by means that would be otherwise used thereby pursuant to the Code of Administrative Procedure. The document shall be considered delivered on day five after the public notice posting.

Section 6

(1) In case of doubts, the Institute shall decide whether a product is governed by the Medical Device Regulation or by the In Vitro Diagnostic Medical Device Regulation, and shall do so either upon request or ex-officio. In case a Commission implementing act pursuant to Article 4 of the Medical Device Regulation or pursuant to Article 3 of the In Vitro Diagnostic Medical Device Regulation is issued when the Institute's decision referred to in sentence one becomes final, the Institute shall forthwith initiate an ex-officio procedure to repeal the decision referred to by sentence one once such implementing act takes effect, if the decision is contrary to this Commission implementing act. The first act to be completed in the procedure to repeal the decision referred to by sentence one is the issuance of a decision; an appeal from the decision in the procedure to repeal the decision referred to by sentence one shall have no suspensory effect.

(2) If the Institute is unable to issue the decision referred to by paragraph (1) sentence one on the basis of available source materials, it shall submit a request referred to under Art. 4(1) of the Medical Device Regulation or under Art. 3(1) of the In Vitro Diagnostic Medical Device Regulation and shall stop the procedure referred to by paragraph (1) sentence one.

(3) The Institute shall issue a general measure by means of which it shall restrict the manufacture or use of a specific type of device pursuant to Art. 5(5) of the Medical Device Regulation or Art. 5(5) of the In Vitro Diagnostic Medical Device Regulation if it finds out that the use of the device poses a risk for the safety of the patient, user or other persons or a risk for public health.

(4) In the issuance of the general measure referred to under paragraph (3), the draft general measure shall be delivered and the general measure announced by means of a public notice on the Institute's noticeboard.

(5) The general measure referred to under paragraph (3) shall take effect on Day 15 of the day of its placement onto the Institute's noticeboard. In case of measures that can brook no delay, the Institute may stipulate an earlier effective date of the general measure, no sooner, however, than as at the moment of its placement on the noticeboard.

Section 7

Medical Device Information System

(1) The Institute is the founder, administrator, and operator of the Medical Device Information System, which is not publicly accessible, unless stipulated otherwise by the Act. The Medical Device Information System is a public administration information system intended primarily for the collection and administration of data and for the submission of notifications and requests to the Institute and, in cases set forth by the Act, also for the provision of information to the public. In those cases, when the Medical Device Information System does not serve for the provision of information to the public, access thereto shall be possible only with guaranteed identity. The Medical Device Information System contains, in particular, data obtained by the Institute

a) from electronic systems referred to under the Medical Device Regulation or the In Vitro Diagnostic Medical Device Regulation;

b) pursuant to Sections 8, 10, 13, and 23 and pursuant to Art. 16(4) of the Medical Device Regulation or pursuant to Art. 16(4) of the In Vitro Diagnostic Medical Device Regulation.

(2) The Medical Device Information System serves for publication, allowing for remote access, of information referred to under Article 33 of the Medical Device Regulation, information referred to under Article 30 of the In Vitro Diagnostic Medical Device Regulation, data about persons who have notified their operation pursuant to Section 23, and data about concerned devices notified pursuant to Section 23(2)(e) and (f).

(3) Upon a manufacturer's request, the Institute shall delete the link between the manufacturer and the servicing person in the Medical Device Information System.

(4) The information referred to under Art. 16(4) of the Medical Device Regulation or under Art. 16(4) of the In Vitro Diagnostic Medical Device Regulation shall be provided by distributors or importers to the Institute via the Medical Device Information System.

(5) It is possible to authorise another person to carry out any acts in the Medical Device Information System. The Power of Attorney may be granted by the principal and accepted by the agent also in electronic format via the Medical Device Information System.

PART THREE

OBLIGATIONS OF THE MANUFACTURER; REPROCESSING OF SINGLE-USE DEVICES; CERTIFICATE OF FREE SALE

Section 8

Obligations of the manufacturer and its authorised representative

(1) A manufacturer or its authorised representative who is established within the territory of the Czech Republic or who places or makes available a device on the market in the Czech Republic, shall be obliged to store and submit to the Institute upon the latter's request any and all information and documentation necessary to demonstrate the conformity of the device in the Czech, Slovak or English language. The manufacturer shall be obliged to ensure that for a device placed on the market within the territory of the Czech Republic, the declaration of conformity referred to under Art. 19(1) of the Medical Device Regulation or under Art. 17(1) of the In Vitro Diagnostic Medical Device Regulation were issued in the Czech, Slovak or English language or translated to any of the aforementioned languages.

(2) A manufacturer who places or makes available a device on the market within the territory of the Czech Republic, shall be obliged to provide the information referred to under Art. 10(11) of the Medical Device Regulation or under Art. 10(10) of the In Vitro Diagnostic Medical Device Regulation, the information referred to under Art. 18(1)(a) to (d) of the Medical Device Regulation, the information referred to under Art. 89(8) of the Medical Device Regulation or under Art. 84(8) of the In Vitro Diagnostic Medical Device Regulation, and the declaration referred to under Annex XIII(1) to the Medical Device Regulation in the Czech language.

(3) Should the manufacturer or its authorised representative fail to meet the obligation stipulated by sentence one of Art. 31(5) of the Medical Device Regulation or the obligation stipulated by sentence one of Art. 28(5) of the In Vitro Diagnostic Medical Device Regulation, the Institute may, in compliance with sentence two of Art. 31(5) of the Medical Device Regulation or in compliance with sentence two of Art. 28(5) of the In Vitro Diagnostic Medical Device Regulation decide to suspend the making available of the concerned device on the market within the territory of the Czech Republic.

(4) A manufacturer of a custom-made device which is established within the territory of the Czech Republic shall be obliged to provide the Institute, via the Medical Device Information System, with the following:

a) information on the commencement of operation within 30 days of the commencement of manufacture of the custom-made medical device;

b) a list of generic groups of manufactured medical devices made available on the market within the

territory of the Czech Republic within 60 days of the commencement of manufacture of the custom-made medical devices;

c) information on cessation of operation.

(5) A manufacturer of a custom-made medical device shall be obliged to submit to the Institute upon the latter's request a list of medical devices made available on the market within the territory of the Czech Republic thereby, for no more, however, than the period of ten years and, for implantable devices, a period of 15 years prior to the day of the request made by the Institute.

(6) By way of the Medical Device Information System, the Institute shall allocate a registration number to each manufacturer of a custom-made device who notified the commencement of its operation pursuant to paragraph (4).

(7) Should the manufacturer breach the obligations stipulated by subparagraph two of Art. 10(14) of the Medical Device Regulation or by subparagraph two of Art. 10(13) of the In Vitro Diagnostic Medical Device Regulation, the Institute, in order to protect public health and patient safety, shall forthwith adopt appropriate restricting or banning measures. The Institute shall adopt the measures referred to by sentence one for the period until the manufacturer begins to cooperate with the Institute or until the manufacturer provides the Institute with complete and correct information referred to under subparagraph one of Art. 10(14) of the Medical Device Regulation or subparagraph one of Art. 10(13) of the In Vitro Diagnostic Medical Device Regulation. The Institute shall issue a decision concerning the measures referred to by sentence one. An appeal from such decision shall have no suspensory effect. The measures referred to by sentence one shall be:

a) suspension or restriction of making the device available on the market;

b) withdrawal; or

c) recall.

Section 9

Reprocessing of a single-use device

(1) Reprocessing of single-use devices is prohibited within the territory of the Czech Republic.

(2) Placing or making available of a reprocessed single-use device on the market within the territory of the Czech Republic and its use within the territory of the Czech Republic is prohibited.

Section 10

Issuance of certificates of free sale

(1) The applicant shall submit an application for the certificate of free sale to the Institute via the Medical Device Information System.

(2) Along with the particulars stipulated by the Code of Administrative Procedure, the application must contain:

a) the primary identifier of the device model (basic UDI-DI) in the UDI system pursuant to Article 27 of the Medical Device Regulation or pursuant to Article 24 of the In Vitro Diagnostic Medical Device Regulation, if it has been allocated; and

b) information as to whether the issuance of the certificate of free sale is required in electronic or paper format.

(3) In the European database of medical devices (hereinafter referred to as the "Eudamed database"), the Institute shall check that the concerned device has been registered and that no change that would prevent the issuance of the certificate of free sale has occurred since the date of

the registration.

(4) By way of the Medical Device Information System, the Institute shall issue the certificate of free sale to the applicant in the form of a certificate referred to by the Code of Administrative Procedure in the Czech and English language in compliance with Article 60 of the Medical Device Regulation or in compliance with Article 55 of the In Vitro Diagnostic Medical Device Regulation, or shall decline the application.

(5) For the purposes of issuance of the certificate of free sale referred to under paragraph (4), the applicant shall also meet the conditions stipulated by Art. 29(4) of the Medical Device Regulation or by Art. 26(3) of the In Vitro Diagnostic Medical Device Regulation.

(6) The application for certificate of free sale may be submitted for a single device or for a group of devices falling within the same generic group.

PART FOUR

CLINICAL EVALUATIONS AND CLINICAL INVESTIGATIONS, PERFORMANCE EVALUATIONS AND PERFORMANCE STUDIES

Ethics committee

Section 11

(1) The ethics committee performs an independent ethics review of the clinical investigation or performance study in order to assess, with emphasis placed upon the ethical aspects, whether the rights, safety, dignity, and quality of life of subjects of clinical investigation or performance study are protected and whether these aspects prevail over any other interests.

(2) The ethics committee shall issue its written opinion on the intention to conduct a clinical investigation or a performance study and shall carry out supervision over their course from the perspective of the objectives referred to under paragraph (1). For this purpose, it shall, in particular, review the professional competence of investigators, including the principal investigator, and the adequacy of the selected procedures and groups of clinical investigation subjects or performance study subjects and shall provide its position by means of the opinion on the clinical investigation or opinion on the performance study and on the documents used to inform clinical investigation subjects or performance study subjects and to obtain their informed consent, independently of the sponsor of the clinical investigation or performance study and of the investigator.

(3) The ethics committee shall carry out supervision over the course of the clinical investigation or over the course of the performance study for which is has issued its favourable opinion, within intervals adequate to the degree of risk for the subjects of the clinical investigation or performance study, no less, however, than on an annual basis, in compliance with paragraph (1) and with the procedures stipulated by Section 13(2). Unless the operation of the ethics committee is taken over by another ethics committee in case of dissolution of the former at the time when the clinical investigation or performance study is ongoing, the favourable opinion of the ethics committee on the conduct of the concerned clinical investigation or performance study shall become void.

Section 12

(1) The ethics committee shall be established by the healthcare provider. The ethics committee may act also as the ethics committee for another healthcare provider, on the basis of a written agreement concluded by and between the healthcare provider. In such a case, the conditions for the operation of the ethics committee shall be catered for by the establishing healthcare provider.

(2) The healthcare provider shall appoint the members of the ethics committee in writing and upon their agreement. An ethics committee shall have at least five members. At least one of the ethics committee members must be a person without healthcare education and without professional scientific qualification in the field of healthcare and at least one member of the ethics committee must be a person who is not in an employee or a similar labour relationship with or in another dependent position

to the healthcare provider that establishes the ethics committee or that operates the healthcare facility where the proposed clinical investigation or performance study is to be conducted, and these two members of the ethics committee must be two different individuals. At least four members of the ethics committee must be educated as medical doctors, dentists, pharmacists or non-medical healthcare professionals pursuant to another legal regulation governing the competence to perform the healthcare profession of a medical doctor, dentist, and pharmacist or a non-medical healthcare professional, and at least three members of the ethics committee must be educated as a medical doctor, dentist or a pharmacist and have the minimum of five years of practical experience in their specialty. The healthcare provider establishing the ethics committee shall ask the individual candidates for ethics committee members for their agreement with their membership in the ethics committee and shall advise them on the obligations of an ethics committee member referred to under paragraph (4); the candidates for ethics committee members shall confirm in writing that they agree with their membership in the ethics committee and that they have been advised on the obligations of an ethics committee member referred to under paragraph (4). The ethics committee members shall elect one of them to be the chairperson of the ethics committee. In order to gain a view on a specific application for opinion, the ethics committee may invite other experts; such experts shall be likewise governed by paragraph (4).

(3) An ethics committee member may only be a person of integrity, aged more than 18 years, whose legal capacity has not been restricted. A person of integrity shall mean a person meeting the conditions of integrity stipulated by another legal regulation governing the competence to perform the healthcare profession of a medical doctor, dentist, and a pharmacist or a non-medical healthcare professional. The natural person shall evidence its integrity by means of an excerpt from the Penal Registry pursuant to another legal regulation governing the Penal Registry, as well as by a document equivalent to an excerpt from the Penal Registry issued by the state the natural person is a citizen of, as well as adequate documents issued by the states within the territory of which the natural person stayed uninterruptedly for more than six months in the last three years. The excerpt from the Penal Registry and the documents evidencing the integrity of the natural person must not be older than three months. In case the state mentioned in sentence three does not issue excerpts from the Penal Registry or an equivalent document or if such document cannot be obtained, the natural person shall submit an affidavit of integrity made thereby in front of a notary or a competent authority of this state. A foreigner who is or was the citizen of another European Union Member State or is or was residing in another European Union Member State, may evidence his/her integrity by an excerpt from the Penal Registry with an attachment containing information included under the Penal Registry of another European Union Member State, rather than by the excerpt from a registry similar to the Penal Registry.

(4) An ethics committee member shall be obliged to:

a) maintain confidentiality with respect to information and facts concerning the course of the clinical investigation or performance study, particularly the condition of health of the subjects of the clinical investigation or performance study and the results of the clinical investigation or performance study learnt thereby in connection with its membership in the ethics committee;

b) forthwith announce any personal interest in the assessed clinical investigation or performance study, or such interest arising;

c) refrain from voicing its opinion on applications for approval of the conduct of the clinical investigation or performance study, in the conduct of which he/she has a personal interest, and to refrain from conducting expert supervision over such clinical investigation or performance study.

(5) Ethics committee membership shall cease to exist:

a) upon giving up of the position of an ethics committee member;

b) upon the death of the ethics committee member; or

c) if the ethics committee member no longer complies with the conditions of membership stipulated by paragraphs (2) to (4).

(6) An ethics committee shall cease to exist, if:

a) its membership structure fails to meet the conditions stipulated by paragraph (2);

b) the healthcare provider who has established it decided on the dissolution of the ethics committee;

c) the healthcare provider who has established it discontinues healthcare service provision; or

d) the following happens in respect of the establishing healthcare provider:
1. the authorisation of the healthcare provider to provide healthcare services has been suspended;
2. the authorisation of the healthcare provider to provide healthcare services has been revoked; or
3. the authorisation of the healthcare provider to provide healthcare services has expired.

Section 13

(1) The healthcare provider shall, via the Medical Device Information System, notify the Institute of the establishment and dissolution of an ethics committee and of changes to its membership and shall do so without unnecessary delay, no later, however, than within 30 days of the date of the establishment or dissolution of the ethics committee or of the change to its membership. The healthcare provider shall provide the information about an ethics committee dissolution also to all sponsors of clinical investigations or performance studies supervised by the ethics committee, and shall do so without unnecessary delay, no later, however, than within five working days of the date of the dissolution of the ethics committee. The notice shall include the name of the ethics committee, contact address, telephone number for a public telephone network, and electronic mail address, the names and surnames of the members of the ethics committee, specifying the field of expertise of the ethics committee members, the name and surname of the chairperson of the ethics committee, and the date of establishment, changes to the membership or dissolution of the ethics committee.

(2) The ethics committee shall operate in compliance with written procedures drafted thereby for this purpose. The written operating procedures shall be approved by all ethics committee members. The procedures for the assessment of applications for opinions on a clinical investigation or performance study and supervision over the course of the clinical investigation or the course of the performance study must be, in case of medical devices, compatible with the procedures for the assessment of an application for clinical investigation authorisation stipulated by the Medical Device Regulation, and, in case of in vitro diagnostic medical devices, it must be compatible with the procedures for the assessment of applications for performance study authorisation stipulated by the In Vitro Diagnostic Medical Device Regulation and it must contain, as the minimum:

a) data about the membership of the ethics committee, including the names and surnames of the members and their qualification, data about the healthcare facility, for which the committee has been established by the healthcare provider;

b) the methods and procedures for the assessment of applications for the opinion of the ethics committee on clinical investigations or performance studies, and for the conduct of ongoing supervision over the clinical investigation or performance study, including the method of planning meetings and notifying ethics committee members of the meetings, and the method of conducting such meetings;

c) procedures for accelerated assessment and issuance of opinions on administrative changes to ongoing clinical investigations or ongoing performance studies;

d) methods of processing of reports from investigators and of information obtained through supervision over the clinical investigation or over a performance study or in another manner;

e) the procedure of issuance of an opinion on a clinical investigation or on a performance study and of its communication to the investigator or healthcare provider; procedures for a review of the opinion and for withdrawal of an opinion; and

f) procedures for meeting the information duties stipulated by the Act.

(3) The healthcare provider shall be obliged to keep any and all records about the operation of the ethics committee established thereby for the period of at least ten years after the end of the clinical investigation or performance study.

(4) In case of dissolution of the ethics committee, the healthcare provider that established the ethics committee shall inform the Institute whether the activities of the dissolved ethics committee have been taken over by another ethics committee. At the same time, it shall provide the Institute with a list of ongoing clinical investigations or performance studies supervised by the dissolved ethics committee and shall specify how the storage and handover of a copy of documentation of the dissolved ethics committee to another ethics committee has been organised.

(5) In case no supervision by another ethics committee has been organised, the ongoing clinical investigation or performance study at the concerned healthcare provider must be suspended until supervision over the clinical investigation or performance study is taken over by another ethics committee. The sponsor of the concerned clinical investigation or performance study shall ensure that recruitment of new subjects of the clinical investigation or performance study be suspended, and that follow-up of previously enrolled subjects of the clinical investigation or performance study continue in compliance with the plan of the clinical investigation or performance study.

(6) The Institute shall keep and publish, via the Medical Device Information System, a list of ethics committees in the Czech Republic, specifying the name of the ethics committee, the contact address of the ethics committee, the field of expertise of the ethics committee members, the date of establishment of the ethics committee, and, where applicable, the date of dissolution of the ethics committee.

Procedure for the issuance of ethics committee opinion

Section 14

(1) Where a clinical investigation or performance study is conducted in a healthcare facility, for which a favourable opinion of the ethics committee established by the healthcare provider who operates the healthcare facility has been issued, the management of the healthcare facility shall arrange for conditions allowing this ethics committee to operate for the duration of the clinical investigation or performance study in this healthcare facility, and, if changes to the ethics committee membership occur, to ensure a flawless carry-on of the ethics committee activities as well as its rights and obligations.

(2) Upon sponsor's request, the ethics committee shall issue an opinion on the clinical investigation or performance study in question. The sponsor shall be obliged to compensate the healthcare provider who established the ethics committee for costs reasonably incurred thereby in connection with the issuance of such opinion.

(3) The ethics committee shall issue its opinion on the clinical investigation or performance study at a meeting which shall be announced in advance in compliance with the working procedures referred to under Section 13(2). The ethics committee shall reach a quorum if at least five ethics committee members are present, of whom one must be a person without healthcare education and without professional scientific qualification in the sphere of healthcare and at least four must be qualified as medical doctors, dentists, pharmacists or non-medical healthcare professionals pursuant to another legal regulation governing the competence to perform the healthcare profession of a medical doctor, dentist and pharmacist or a non-medical healthcare professional, and at least one of the members with healthcare education must be a person who is not in an employee or a similar labour relationship with or in another dependent position to the healthcare provider establishing the ethics committee or operating the healthcare facility where the proposed clinical investigation or performance study is to be conducted. The ethics committee shall act by an absolute majority of the votes cast by the attending members, who may vote as stipulated in sentences five and six. In the event of a tied vote, the chairperson shall have the casting vote. The vote may be cast only by those members of the ethics committee who have been involved in the entire discussion concerning the specific application for the issuance of an opinion. Where the investigator of the concerned clinical investigation or performance study is, at the same time, a member of the ethics committee, he/she shall withdraw from the discussions concerning the application.

(4) The ethics committee shall be obliged to minute its meetings. The minutes of the ethics committee meetings shall contain the date, hour, and venue of the meeting, a list of attending ethics committee members, a list of other invited attendees, major issues on the agenda, the approved opinion including a record of the outcome of the voting about this opinion, specifying the votes of the ethics committee members, a record of announcements of potential conflicts of interests of the ethics committee members, and a signature of at least two members of the ethics committee.

Section 15

(1) Where medical devices are concerned, the ethics committee, in the preparation of its opinion, shall assess, in compliance with the ethical principles and through methods stipulated by chapter I of Annex XV to the Medical Device Regulation, whether the conditions set forth by Art. 62(4)(d) to (k) of the Medical Device Regulation have been met, and, moreover, shall assess

a) the rationale of the clinical investigation and its design;

b) whether the evaluation of the expected benefits and risks is acceptable and whether its conclusions are justified;

c) the clinical investigation plan drafted in compliance with chapter II(3) of Annex XV to the Medical Device Regulation;

d) whether the investigator and his/her staff meet the requirements stipulated by Art. 62(6) of the Medical Device Regulation;

e) the Investigator's Brochure, drafted in compliance with chapter II(2) of Annex XV to the Medical Device Regulation;

f) whether the facility of the healthcare provider where the clinical investigation is to be conducted meets the requirements stipulated by Art. 62(7) of the Medical Device Regulation;

g) where an investigation with subjects of restricted capacity is concerned, whether the method of information provision pursuant to Art. 63(2) of the Medical Device Regulation is adequate to the ability of these persons to understand the information;

h) whether compensation for injuries of the clinical investigation subjects arising from the clinical investigation has been sufficiently catered for, reviewing, in particular, any and all insurance policies covering mandatory compensation of injuries concluded in compliance with Section 19(1);

i) the method of recruitment of the clinical investigation subjects;

j) the text of the informed consent and other written information provided to the subjects of the clinical investigation.

(2) Where in vitro diagnostic medical devices are concerned, in the preparation of its opinion, the ethics committee shall assess, in line with the ethical principles and through methods stipulated by Annex XIV to the In Vitro Diagnostic Medical Device Regulation, whether the conditions set forth by Art. 58(5)(d) to (k) of the In Vitro Diagnostic Medical Device Regulation have been met, and, moreover, shall assess

a) the rationale of the performance study and its design;

b) whether the evaluation of the expected benefits and risks is acceptable and whether its conclusions are justified;

c) the performance study plan drafted in compliance with Part A of Annex XIV to the In Vitro Diagnostic Medical Device Regulation;

d) whether the investigator and his/her staff meet the requirements stipulated by Art. 58(7) of the In

Vitro Diagnostic Medical Device Regulation;

e) the Investigator's Brochure, drafted in compliance with Chapter I(2) of Annex XIV to the In Vitro Diagnostic Medical Device Regulation;

f) whether the facility of the healthcare provider where the performance study is to be conducted meets the requirements stipulated by Art. 58(8) of the In Vitro Diagnostic Medical Device Regulation;

g) where a performance study with subjects of restricted capacity is concerned, whether the conditions for the conduct of the performance study stipulated by Art. 60(1) of the In Vitro Diagnostic Medical Device Regulation have been met;

h) whether compensation for injuries of the performance study subjects arising from the performance study has been sufficiently catered for, reviewing, in particular, any and all insurance policies covering mandatory compensation of injuries concluded in compliance with Section 19(1);

i) the method of recruitment of the performance study subjects;

j) the text of the informed consent and other written information provided to the subjects of the performance study.

(3) In its assessment of compensation and insurance, the ethics committee shall always assess whether

a) compensation for injuries arising for the subjects of the clinical investigation or performance study from their participation in the clinical investigation or performance study has been sufficiently catered for by means of an insurance policy as per Section 19(1);

b) the obligation to compensate injuries for the investigator and sponsor has been sufficiently covered by an insurance policy as per Section 19(1), and, if applicable, whether the liability insurance of the investigator or sponsor forms part of their labour relationships;

c) the compensation does not exceed the expenditures incurred by the clinical investigation or performance study subject or by the investigator in association with their participation in the clinical investigation or in the performance study and, moreover, whether the remuneration for investigators has been made known in advance and whether the sponsor has submitted a written notification of the amount of such remuneration along with the application.

(4) In case of clinical investigations or performance studies, for which the informed consent of the subject of the clinical investigation or performance study cannot be obtained prior to the subject's enrolment in the clinical investigation or performance study, the ethics committee shall assess the methods provided by the protocol to ensure that the informed consent is requested from the subject’s legal guardian, carer or a representative of the members of the household appointed by court or from the subject himself/herself pursuant to the Medical Device Regulation or the In Vitro Diagnostic Medical Device Regulation, and shall consider whether it is expedient to condition the enrolment of each individual subject by its consent. In case the integrity of a subject of clinical investigation or performance study who is incapable of judgment is to be affected in a manner resulting in permanent, unavoidable, and serious consequences or in a manner bearing a serious jeopardy to the subject's life or health, the clinical investigation or performance study may be conducted only if permitted by court[5)].

Section 16

(1) The ethics committee shall issue an opinion on a clinical investigation or performance study on the basis of a written application and following assessment of the submitted documentation. The application shall be submitted to the concerned ethics committee by the sponsor. The required documents shall be submitted to the ethics committee in the Czech language; the ethics committee may allow submission of the required documents also in another language, except for the informed consent and summary plan of the clinical investigation or performance study.

(2) Along with the application for opinion on the clinical investigation or performance study, the

sponsor shall submit source materials necessary for the assessment of the clinical investigation or performance study by the ethics committee, in particular, documentation allowing the ethics committee to assess facts referred to under Section 19(1). The ethics committee is entitled to request further documents and additional information necessary for the assessment of the concerned facts from the sponsor. Where the ethics committee requests documents or information referred to under sentence two, the timeline for the issuance of the ethics committee opinion referred to under paragraph (3) shall be suspended until the delivery of the documents and information to the ethics committee.

(3) The ethics committee shall issue the sponsor with a written justified opinion on the concerned clinical investigation or performance study within 60 days of the delivery of the application. The opinion of the ethics committee shall contain

a) identification data about the assessed clinical investigation or performance study, particularly the title of the clinical investigation or performance study, identification of the sponsor and the clinical investigation or performance study site, clinical investigation or performance study protocol number, and, where applicable, the identification number of the clinical investigation or performance study from the Eudamed database, the date of delivery of the application for clinical investigation or performance study authorisation, and a list of clinical investigation or performance study sites in respect of which the ethics committee has provided its opinion and carries supervision over;

b) a list of ethics committee members and specification of their specialty;

c) a list of assessed documents, including their identification;

d) a record of the outcome of the vote, statement as to whether the ethics committee issues its favourable opinion on or declines the clinical investigation or performance study, giving a rationale thereof;

e) the date of issuance of the opinion and signature of at least two members of the ethics committee authorised for this purpose; and

f) in case of clinical investigations or performance studies where it is not possible to obtain the subject's informed consent prior to his/her enrolment in the clinical investigation or performance study, an exlicit statement of the ethics committee whether it agrees with the procedure for subject enrolment specified in the protocol, specifying whether it preconditions the enrolment of each individual subject by the consent of the ethics committee; where the ethics committee does precondition the enrolment of each individual subject by the consent of the ethics committee, it shall also specify the method to be employed by the investigator to request such consent and the method to be employed by the ethics committee in providing the concerned position without any delay.

Section 17

The sponsor shall be obliged to notify intended substantial modifications to a clinical investigation or performance study to the ethics committee which issued its opinion on this clinical investigation or performance study. Such notification must be made in writing and contain the reasons for the variation. Along with the notification, the sponsor shall submit the proposed redrafted parts of the documentation affected by the variation and by the amendment to the protocol. Where a minor variation is concerned, the sponsor shall forthwith inform, by way of electronic communication, the Institute and the ethics committee which issued its opinion on the concerned clinical investigation or performance study. The course of action to be employed when submitting an application for the opinion of the ethics committee on a substantial variation to the clinical investigation or performance study, when assessing the substantial variation to the clinical investigation or performance study, and when issuing an opinion thereupon, shall be analogous to the procedure outlined by Sections 14 to 16.

Section 18

(1) The ethics committee shall revoke or suspend its favourable opinion, if it learns of facts relevant for the safety of subjects of the clinical investigation or performance study or if the sponsor or investigator seriously breaches the conditions of conduct or design of the clinical investigation or performance study, in respect of which the ethics committee issued its favourable opinion. Except for

cases when the safety of the subjects of the clinical investigation or performance study is jeopardised, the ethics committee shall request the position of the sponsor or, if applicable, the investigator, prior to doing so.

(2) The ethics committee shall forthwith notify in writing the investigator, sponsor and Institute of the revocation or suspension of its favourable opinion referred to under paragraph (1). The revocation or suspension of the favourable opinion of the ethics committee shall contain

a) identification data of the clinical investigation or performance study, in particular, the title of the clinical investigation or performance study, identification of the sponsor and clinical investigation or performance study sites, for which the favourable opinion is being revoked or suspended, the number of the protocol of the clinical investigation or performance study, and, where applicable, the protocol identification number from the Eudamed database;

b) a rationale for the revocation or suspension of the favourable opinion;

c) measures for terminating the clinical investigation or performance study, particularly concerning a switch to another treatment option, where the favourable opinion has been revoked or suspended for reasons concerning a jeopardy to the safety of the subjects of the clinical investigation or performance study, unless such options have been specified in the protocol of the clinical investigation or performance study;

d) the date of revocation or suspension of the favourable opinion and signatures of at least two members of the ethics committee authorised for this purpose.

General provisions on clinical evaluations and clinical investigations and performance evaluations and performance studies

Section 19

(1) The sponsor shall be responsible to the subject of a clinical investigation or performance study for injuries suffered by the latter due to his/her participation in the clinical investigation or performance study conducted within the territory of the Czech Republic. For these cases, the sponsor shall be obliged to contract a liability insurance prior to the start of the clinical investigation or performance study covering injuries arising from the conduct of the clinical investigation or performance study; such insurance must be contracted for the entire duration of the conduct of the clinical investigation or performance study and cover the entire scope of the sponsor’s liability. The scope of the insurance and the contracted maximum cover amount must be adequate to the risks associated with the conducted clinical investigation or performance study.

(2) In respect of the insurance contracted pursuant to paragraph (1), the insurer shall be authorised to withdraw from the insurance policy or cancel the insurance no later than as at the day immediately preceding the planned clinical investigation or performance study start date. During the period from the expiry of this timeline until the end of the clinical investigation or performance study, the insurer may not withdraw from the insurance policy or cancel the insurance. Should the insurer identify facts that would otherwise result in a withdrawal from the insurance policy or cancellation of the insurance at the time of conduct of the clinical investigation or performance study, it shall be authorised to request from the sponsor compensation for the provided performance up to the agreed maximum cover sum. The sponsor’s obligation to compensate the subject of the clinical investigation or performance study for injury shall not be prejudiced hereby.

(3) In case the insurer has withdrawn from the insurance policy or cancelled insurance as referred to under paragraph (2), it shall forthwith inform the Institute to this effect. The information shall include the identification of the insurance policy it has withdrawn from, or the cancelled insurance, the parties thereto, and the reason for withdrawal from the insurance policy or for the cancellation of the insurance.

Section 20

(1) For the purposes of its potential bankruptcy or cessation of operation, the sponsor shall be

obliged to arrange for the storage of documentation

a) of the clinical investigation referred to by the Medical Device Regulation for the period stipulated by Annex XV to the Medical Device Regulation, where medical devices governed by the Medical Device Regulation are concerned; or

b) of the performance study referred to by the In Vitro Diagnostic Medical Device Regulation for the period stipulated by Annex XIV to the In Vitro Diagnostic Medical Device Regulation where in vitro diagnostic medical devices are concerned;

the sponsor shall be obliged to evidence the method of fulfilling this obligation when submitting the application for clinical investigation authorisation or for performance study authorisation.

(2) The sponsor shall be obliged to inform the Institute and the concerned ethics committee about the commencement of the clinical investigation or performance study. In the course of the clinical investigation or performance study, the sponsor shall be obliged to provide the Institute and the concerned ethics committee with an annual report on the progress and evaluation of safety of the clinical investigation or performance study no later than by 31 January of the following year.

(3) Where significant new information that could affect the evaluation of benefits and risks of the investigational device arises, the sponsor shall forthwith inform the Institute, the ethics committee, and clinical investigation subjects by means of an amended text of the existing informed consent. In such a case, where an in vitro diagnostic medical device is being assessed in a performance study not requiring an informed consent, the sponsor shall forthwith inform the Institute and the ethics committee.

(4) The opinion of the ethics committee must form part of the documentation to be submitted along with the application for clinical investigation authorisation or application for performance study authorisation or application for authorisation of a substantial variation to clinical investigation or application for authorisation of a substantial variation to performance study.

(5) In compliance with Art. 70(7)(a) of the Medical Device Regulation, a clinical investigation referred to under Art. 62(1) of the Medical Device Regulation or, in compliance with Art. 66(7)(a) of the In Vitro Diagnostic Medical Device Regulation, a performance study referred to under Art. 58(1) and (2) of the In Vitro Diagnostic Medical Device Regulation, may not be commenced without a prior authorisation obtained from the Institute. The Institute shall notify the sponsor of the authorisation of the clinical investigation within timelines stipulated by Art. 70(7)(b) of the Medical Device Regulation or the sponsor of a performance study within timelines stipulated by Art. 66(7)(b) of the In Vitro Diagnostic Medical Device Regulation. The Institute's decision on authorisation of a clinical investigation shall be valid for one year of the date on which such decision becomes final.

(6) The timelines stipulated by Art. 70(1) and (3) of the Medical Device Regulation and by Art. 66(1) and (3) of the In Vitro Diagnostic Medical Device Regulation shall be extended by five days. The timelines stipulated by Art. 75(3) of the Medical Device Regulation and by Art. 71(3) of the In Vitro Diagnostic Medical Device Regulation shall be extended by seven days.

(7) Where the Institute, in its assessment of the application for authorisation of a substantial variation to clinical investigation as per Art. 75(2) of the Medical Device Regulation finds out that the submitted application is incomplete, it shall invite the sponsor to amend it. In such a case, the timeline stipulated by Art. 75(3) of the Medical Device Regulation shall be suspended for the time from the date of issue of the first invitation for amendment until the date of receipt of the properly amended application. In case of negative assessment, the Institute shall decline the application for authorisation of a substantial variation to the clinical investigation by means of a decision without providing the sponsor with an opportunity to comment on the source materials for the decision. A similar procedure shall apply to clinical investigations referred to under Art. 74(1) and Article 82 of the Medical Device Regulation.

(8) Where the Institute, in its assessment of the application for authorisation of a substantial variation to performance study referred to by Art. 71(2) of the In Vitro Diagnostic Medical Device Regulation finds out that the submitted application is incomplete, it shall invite the sponsor to amend it. In such a case, the timeline stipulated by Art. 71(3) of the In Vitro Diagnostic Medical Device

Regulation shall be suspended for the time from the date of issue of the first invitation for amendment until the date of receipt of the properly amended application. In case of negative assessment, the Institute shall decline the application for authorisation of a substantial variation to the performance study by means of a decision without providing the sponsor with an opportunity to comment on the source materials for the decision. A similar procedure shall apply to performance studies referred to under Art. 71(1) of the In Vitro Diagnostic Medical Device Regulation.

Section 21

Special provisions governing subjects of clinical investigations or performance studies

(1) Unless stipulated otherwise below, a subject of a clinical investigation or performance study may not be a person in custody or in forensic detention or a person placed by court decision in a facility with restricted personal liberty or a person provided with healthcare services without his/her consent.

(2) Where a clinical investigation or performance study has been initiated on a person who is taken into custody or forensic detention in the course of testing, such person must be forthwith excluded from the clinical investigation or performance study. This shall not apply to situations where the termination of the person's participation in the clinical investigation or performance study would jeopardise the person's health. In such a case, the Prison Service of the Czech Republic shall allow this person to continue his/her participation in the clinical investigation or performance study as long as necessary and shall provide the required cooperation for this purpose.

(3) Where practicable, the opinion of a minor or of a major incapable of protecting his/her interest in full, on potential participation in a clinical investigation or performance study shall be also sought. The identified opinion of this person, and, if applicable, the reason why it could not be established, and, if applicable, the consent of the person's legal guardian, carer or a representative of the members of the household appointed by court shall be recorded in the medical documentation kept for this person.

Section 22

Requirements governing other clinical investigations

(1) The sponsor of another clinical investigation referred to under Article 82 of the Medical Device Regulation must prepare documentation stipulated by chapter II(2) and (3) of Annex XV to the Medical Device Regulation.

(2) The sponsor of another clinical investigation referred to under Article 82 of the Medical Device Regulation shall contract insurance covering the obligation of indemnification for injuries arising from the conduct of the clinical investigation pursuant to Section 19(1) and shall submit to the Institute the proof of insurance cover as per chapter II(4.3) of Annex XV to the Medical Device Regulation.

(3) Sixty days prior to clinical investigation commencement, the sponsor of another clinical investigation referred to under Article 82 of the Medical Device Regulation shall be obliged to notify the Institute via the Medical Device Information System of its intension to conduct the clinical investigation. The notification shall include also the submission of the documentation referred to under chapter II(1), (2), (3), (4.2), and (4.4) of Annex XV to the Medical Device Regulation. The clinical investigation may be commenced after the expiry of the 60 days of its notification, unless the Institute decides otherwise. Details concerning the particulars of the notification are set forth by the implementing legal regulation; this notification shall contain data identifying the clinical investigation, the sponsor of the clinical investigation, and the site where the clinical investigation is to be conducted, and the planned start and end dates of the clinical investigation.

(4) The sponsor of another clinical investigation referred to under Article 82 of the Medical Device Regulation shall be obliged to notify to the Institute via the Medical Device Information System any serious adverse events referred to under Art. 2(58) of the Medical Device Regulation. Article 80 of the Medical Device Regulation shall be adequately applied to the notification of a serious adverse

event of another clinical investigation. The implementing legal regulation stipulates the details of the particulars of the notification; this notification shall contain data identifying the clinical investigation, the sponsor of the clinical investigation, and a description of the serious adverse event.

(5) The sponsor shall be obliged to notify the Institute via the Medical Device Information System of the end and conclusions of another clinical investigation as per Article 82 of the Medical Device Regulation no later than within 15 days of the end of the clinical investigation, providing the conclusions within three months of its end. The end and the summary of another clinical investigation shall be notified via the Medical Device Information System. The report from another clinical investigation shall contain data identifying the clinical investigation, the sponsor of the clinical investigation, the signature of the investigator, and a critical assessment of all data collected during this clinical investigation. The notification shall contain data identifying the clinical investigation, the sponsor of the clinical investigation, the site where the clinical investigation was conducted, and the clinical investigation end date. Details concerning the particulars of notification of and report from another clinical investigation are stipulated by the implementing legal regulation.

(6) Art. 72(5) of the Medical Device Regulation shall be adequately applied also to other clinical investigations referred to under Article 82 of the Medical Device Regulation. In the interest of protection of the life and health of clinical investigation subjects, the Institute may decide not to authorise the commencement of the clinical investigation or to early terminate or suspend an ongoing clinical investigation on the basis of findings from its ex-officio activities.

(7) The sponsor of another clinical investigation referred to under Article 82 of the Medical Device Regulation shall be obliged to notify to the Institute via the Medical Device Information System substantial modifications to the documentation of the clinical investigation pursuant to Art. 75(1) of the Medical Device Regulation and the written approval of the ethics committee for these modifications, no later than within 30 days of their implementation. A substantial variation may be implemented after the expiry of 30 days of the notification, unless the Institute decides otherwise. The notification shall contain data identifying the clinical investigation, the sponsor of the clinical investigation, a description of the substantial modifications, and the planned date of their implementation. The clinical investigation documentation with highlighted changes shall form part of the notification. Details of the particulars of the notification are stipulated by the implementing legal regulation.

PART FIVE

OBLIGATIONS OF DISTRIBUTORS AND PERSONS SERVICING DEVICES

Section 23

(1) A distributor and person servicing devices shall be obliged to notify the Institute via the Medical Device Information System of their operation of a distributor or person servicing devices prior to the commencement of such operation. This obligation shall not be applicable to a person servicing exclusively risk class I medical devices or risk class A in vitro diagnostic medical devices and to a distributor supplying exclusively risk class I medical devices or risk class A in vitro diagnostic medical devices or supplying devices solely to the user who is not a healthcare provider.

(2) The notification referred to under paragraph (1) must contain

a) identification of the notifier; for natural persons, the name(s), surname, identification number, registered office address, telephone number, contact electronic mail address, data mailbox address if established pursuant to another legal regulation shall be provided; for legal persons, the business name, identification number, registered office address, address of data mailbox established pursuant to another legal regulation shall be provided;

b) identification of the notifier’s legal representative, if the notifier has such representation; for natural persons, the name(s), surname, address of permanent residence, or, if applicable, mailing address, telephone number, contact electronic mail address, data mailbox address if established pursuant to another legal regulation shall be provided; for natural persons–entrepreneurs, the identification number and registered office address shall be, moreover, specified; for legal persons, the business name, identification number, registered office address, and address of data mailbox established

pursuant to another legal regulation shall be provided;

c) the name(s), surname, telephone number in a public telephone network, and electronic mail address of the appointed contact person;

d) identification of the operation being notified;

e) for a distributor in respect of devices that the distributor intends to supply onto the market within the territory of the Czech Republic, except for risk class I medical devices and risk class A in vitro diagnostic medical devices,
1. the primary identifier of the device model (basic UDI-DI) in the UDI system pursuant to Part C of Annex VI to the Medical Device Regulation where a medical device is concerned, or pursuant to Part C of Annex VI to the In Vitro Diagnostic Medical Device Regulation where an in vitro diagnostic medical device is concerned;
2. intended purpose of the device[6)] specified in the instructions for use;

f) for a person servicing devices
1. a list of the single registration numbers of device manufacturers[7)], for which it intends to conduct servicing; and
2. a copy of a document evidencing training in compliance with Section 45(4)(a) or in compliance with Section 46(2)(a) from each manufacturer or the person authorised thereby, and a copy of the authorisation of this person by the manufacturer; these documents shall not be required if the service is being conducted directly by the manufacturer of the device in question.

(3) The obligation to meet the particulars of notification referred to under paragraph (2)(e) shall not be applicable to providers of pharmaceutical care.

Section 24

(1) The Institute shall allocate a registration number to any distributor and person servicing devices who notified their operation pursuant to Section 23 (hereinafter referred to as "notified person"). Where a single person notifies more than one operation hereunder, it shall be allocated one registration number only.

(2) The Institute shall delete the data notified pursuant to Section 23 from the Medical Device Information System, if requested to do so by the person who submitted the notification, and shall advise the latter to this effect by means of a notice.

(3) Where the Institute on the basis of its official operation finds out that the data notified pursuant to Section 23 do not reflect reality, it shall invite the person who has notified these data to amend the situation within a timeline stipulated by the Institute. After the expiry of this timeline, the Institute shall decide about deletion of the data notified pursuant to Section 23 from the Medical Device Information System; the Institute’s decision shall be the first act in the procedure.

Section 25

(1) The notified person shall be obliged to notify a change to the data referred to under Section 23 via the Medical Device Information System within 30 days of the date when the change occurred. Notification of the change of data shall be considered as confirmation of the accuracy of any other notified data referred to under sentence one of paragraph (2). The obligation to notify changes of data pursuant to sentence one shall not apply to changes of data the validity of which may be verified via remote access to basic registries.

(2) Within the timeline of one year of the date of notification as per Section 23 or of the date of the last confirmation of accuracy referred to under sentence one of paragraph (1), the notified person shall be obliged to confirm the accuracy of the notified data. Within 30 days prior to the expiry of the timeline specified in sentence one, the Institute shall send, via the Medical Device Information System, a reminder of the necessity to confirm the accuracy of the notified data to the notified person.

(3) In case of failure to confirm the accuracy of the data within the timeline referred to under

sentence one of paragraph (2), the data of the notified person in the Medical Device Information System shall be considered invalid and shall no longer be published in the Medical Device Information System. The Institute shall inform the notified person to this effect by means of a notice. Invalidated data may be refreshed upon request of the concerned entity within six months of the date of their invalidation. Where data referred to under sentence one are invalidated, the notified person shall not be the notified person for the operation in respect of which it failed to confirm the accuracy of the notified data as per sentence one of paragraph (2).

(4) The data notified pursuant to Section 23 shall continue to be kept in the Medical Device Information System for the period of three years of the date of their invalidation pursuant to paragraph (3). After the expiry of this timeline, the data shall be removed from the system.

Section 26

(1) Supply of a device referred to under Section 28(3) or of an vitro diagnostic medical device, except for a medical device intended by the manufacturer for self-testing, and a diagnostic medical device of risk class A to a user who is a lay person pursuant to Art. 2(38) of the Medical Device Regulation or pursuant to Art. 2(31) of the In Vitro Diagnostic Medical Device Regulation, is prohibited.

(2) In case of distribution of a device onto the market within the territory of the Czech Republic, the distributor shall be obliged to supply the device along with instructions for use in the Czech language, if the manufacturer has issued instructions for use.

(3) Where the importer fails to meet the obligation stipulated by Art. 31(5), sentence one of the Medical Device Regulation or the obligation stipulated by Art. 28(5), sentence one of the In Vitro Diagnostic Medical Device Regulation, the Institute may, in compliance with Art. 31(5), sentence two of the Medical Device Regulation or in compliance with Art. 28(5), sentence two of the In Vitro Diagnostic Medical Device Regulation, decide about suspending the supply of the concerned device onto the market within the territory of the Czech Republic.

Section 27

Good storage practice

(1) For the purposes hereof, good storage practice shall mean a suite of rules ensuring that the transportation and storage of a device be carried out in compliance with the manufacturer’s instructions and minimum requirements for the device safety. The minimum requirements for device safety are stipulated by the implementing legal regulation.

(2) The distributor and the importer shall be obliged to observe good storage practice.

PART SIX

PRESCRIBING AND DISPENSING OF DEVICES

TITLE I

PRESCRIBING OF DEVICES

Section 28

Basic principles governing the prescribing of devices

(1) Devices shall be prescribed during the provision of healthcare services by a medical doctor or by a dentist (hereinafter referred to as the "physician") or by another healthcare professional with specialised or special expert competence pursuant to the Act on Non-Medical Healthcare Professions (hereinafter referred to as the "prescriber") on medical prescription, which shall be

a) an order for a specific patient issued following agreement with the patient in electronic format (hereinafter referred to as the "electronic order");

b) an order for a specific patient issued in paper format (hereinafter referred to as the "paper order"); or

c) a request form for devices to be used during the provision of healthcare services.

(2) Devices are prescribed on medical prescription also by veterinary doctors in the provision of veterinary care pursuant to the Veterinary Act[8)].

(3) A device which may jeopardise the health or life of people even if used in compliance with its intended purpose, if not used under physician's supervision, may be dispensed on medical prescription issued by a physician or veterinary doctor only. The list of such devices is stipulated by the implementing legal regulation.

(4) A device shall be also dispensed on electronic order or on paper order in case the patient is entitled to its reimbursement pursuant to the act governing public health insurance[9)].

(5) The electronic or paper order may be used with the dispensing person within 30 days of its issue, unless specified otherwise by the prescriber, no later, however, than within one year.

(6) A paper order may not bear any symbols or elements restricting the readability of the completed data, data about other healthcare provider or dispensing persons or any advertising statements. A blank paper order form must not be stamped with the stamp of the healthcare provider.

(7) A paper order shall show data identifying the prescriber, the patient for whom the prescribed device is intended, the prescribed device, specifying the number of packs of the prescribed device, and the health insurance company, if the device is to be reimbursed from the public health insurance system. An implementing legal regulation stipulates the exact scope and structure of data to be shown on a paper order.

(8) Where the reimbursement of a device prescribed on a paper order is preconditioned by approval by the concerned health insurance company,

a) the health insurance company shall make a note on the order reading "Approved by health insurance company" or "Not approved by health insurance company", the date of the decision, the decision file number, signature, and imprint of the stamp of the health insurance company;

b) on the basis of a written approval by the health insurance company, the prescriber shall make a note on the order reading "Approved by health insurance company", the date of the health insurance company's decision on approval of the reimbursement, and decision file number; or

c) on the basis of a written approval of repeat prescription by the health insurance company, the prescriber shall make a note on the order reading "Approved by health insurance company", the date of the health insurance company's decision on approval of the repeat reimbursement, and decision file number.

(9) The prescriber shall file the written approval or a document evidencing the written approval of the health insurance company referred to under paragraph (8)(b) or (c) to the patient's medical documentation no later than within five working days of its delivery.

(10) Where the reimbursement of a device prescribed on an electronic order is preconditioned by approval by the concerned health insurance company, the health insurance company shall confirm for the prescriber, via the ePrescription system, whether the conditions under which reimbursement of the prescribed device may be claimed have been met[10)]. The confirmation referred to under sentence one shall not be made for electronic orders for devices for which the health insurance company has already confirmed its consent with repeat reimbursement of the concerned device for the specific patient via the ePrescription system. The confirmation referred to under sentence one may also include a requirement that upon dispensing, the patient be provided with a device other than the prescribed one within the circulatory system[11)].

(11) Where a device the reimbursement of which is preconditioned by approval by the concerned health insurance company is concerned, and the prescriber is a doctor of the Prison Service of the Czech Republic, the order shall be sent by this doctor to the concerned health insurance company for confirmation.

(12) Where the prescriber, having regard to the patient's condition of health, or the health insurance company in its approval of the device reimbursement from public health insurance[9)] insist on dispensing the prescribed device, they shall make a note on the paper order reading "Replacement not allowed" or activate the "No replacement" flag on the electronic order.

Section 29

Electronic order

(1) An electronic order is generated, changed or cancelled in the ePrescription system on the basis of a request of the prescriber, which contains data necessary for the generation, change or cancellation of the electronic order. The request for electronic order generation shall always contain information about the method of handing over the identifier of the electronic order (hereinafter referred to as "electronic order identifier") selected by the patient.

(2) In case of a device reimbursed from the public health insurance system, the prescriber's request for electronic order generation must always contain a numeric identifier of the prescribed device allocated thereto by the Institute pursuant to the Act on Public Health Insurance[9)]. A device that has not been allocated such numeric identifier, may be prescribed on electronic order by a physician only.

(3) In case the prescriber's request for electronic order generation contains all of the required data, the Institute shall generate the electronic order via the ePrescription system and shall forthwith and without consideration inform the prescriber about the electronic order identifier borne by the electronic order. In case the patient requires that the electronic order identifier be sent thereto directly from the ePrescription system, the Institute shall provide it via the system and without consideration also to the patient.

(4) The identifier of the electronic order shall be provided to the patient without consideration; on hand-over, no specific healthcare provider may be preferred and the patient's right to select the dispensing person must not be hindered, except for devices safeguarded by the health insurance company pursuant to the Act on Public Health Insurance[12)]. Unless the patient chooses otherwise, the electronic order identifier shall be provided thereto by means of a paper form. The patient may choose to have the electronic order identifier sent thereto free of charge in a manner other than that mentioned in sentence two, specifically by:

a) a data message sent to the patient's electronic mail address using the central electronic order repository service;

b) a text message sent to the patient's mobile phone device using the central electronic order repository service;

c) a data message using a web or mobile application of the ePrescription system made available by the Institute;

d) a data message sent on the basis of agreement with the prescriber to the patient's electronic mail address using the prescriber's information system service; or

e) a text message sent on the basis of agreement with the prescriber to the mobile phone number of the patient's mobile phone device using the prescriber's information system service.

(5) Regardless of the method of its hand-over, the electronic order identifier must not be accompanied by any statement of advertising nature.

(6) The implementing legal regulation stipulates:

a) the procedure and conditions for communication of prescribers and dispensing persons with the ePrescription system;

b) the form of electronic order identifier provided by the Institute to prescribers and patients via the ePrescription system;

c) the method and conditions of submission and processing of requests for generation, change, and cancellation of electronic orders;

d) the scope of data necessary for the generation, change, and cancellation of electronic orders and particulars thereof;

e) the procedure and conditions for the communication of identification data referred to under Section 31(3)(b) and Section 31(4).

Section 30

Central electronic order repository

(1) The Institute shall establish, administer, and operate a central electronic order repository as part of the ePrescription system. By means of the electronic prescription central repository, the Institute safeguards the collection and storage of

a) electronic orders;

b) records on dispensing of devices on electronic order, including information about the actual device that was dispensed;

c) information concerning the handling of electronic orders.

(2) Via the ePrescription system, the Institute shall, without consideration, provide for the following:

a) immediate provision of the electronic order identifier to the prescriber and, where applicable, also to the patient upon request of the latter;

b) constant access to the electronic order on the basis of which the prescribed device is to be dispensed for the dispensing person;

c) constant access for the prescriber to electronic orders on which the prescriber prescribed devices;

d) constant access for the dispensing person to electronic orders on the basis of which devices were dispensed by this dispensing person;

e) access for the health insurance company to those electronic orders on which its insureds were dispensed devices reimbursed from public health insurance;

f) access for the Ministry to electronic orders on which devices were prescribed for persons whose healthcare services are paid for by the state.

(3) Via the ePrescription system, the Institute shall process

a) the name(s), surname, date of birth, address of residence of the prescriber and his/her contact details and identification data of the healthcare provider, within the scope of whose operation the prescriber provides healthcare services, to the extent of its name, address of the healthcare facility, and site identification number, if allocated by the health insurance company;

b) the name(s), surname, date of birth, address of residence of the individual dispensing the device (hereinafter referred to as the "dispensing individual") and its contact details and identification data of

the dispensing person to the extent of its name, address, and contact details;

c) identification data of the patients, to the extent provided on the medical prescription;

d) data about prescribed and dispensed devices, including the name, quantity, and numeric identification of the device, if allocated by the Institute.

(4) The Institute shall store the information kept in the central electronic order repository, including data listed under paragraph (3), for the period of ten years of the expiry of the electronic order. After the expiry of this period, any information associated with such electronic order shall be removed from the ePrescription system.

Section 31

Access to the central electronic order repository

(1) The prescriber and the dispensing individual shall communicate with the central electronic order repository directly, via the ePrescription system, or via a communication interface of this system and the information system of the prescriber or dispensing individual.

(2) The physician who prescribes the device, and the pharmacist who dispenses the device in the provision of healthcare services in a pharmacy, shall access the ePrescription system in a manner specified by the Act on Pharmaceuticals.

(3) A person other than the persons listed under paragraph (2) authorised to prescribe or dispense the device shall access the ePrescription system via an access certificate of the healthcare provider within the scope of which he/she provides healthcare services, of an operator of an optician's outlet or a person with whom the health insurance company has concluded a contract on dispensing pursuant to the act governing public health insurance; and

a) via the national Identification and Authentication Point;

b) by providing the identification data of this person by the healthcare provider within the scope of which this person provides healthcare services, by the operator of an optician's outlet or person with whom the health insurance company has concluded a contract on dispensing pursuant to the act governing public health insurance; or

c) via access data for the ePrescription system allocated by the Institute pursuant to the Act on Pharmaceuticals.

(4) The person authorised to prescribe or dispense a device referred to under paragraph (3) shall, moreover, access the ePrescription system also via the National Identification and Authentication Point, if the healthcare provider within whose scope this person provides healthcare services, the operator of an optician's outlet or a person with whom the health insurance company has concluded a contract on dispensing pursuant to the act governing the public health insurance, has provided the Institute with the identification data of such person in advance and in situations concerning

a) the prescribing of a device in the provision of health care in the patient's own social environment; or

b) the dispensing of a device in an optician's outlet or at a person's with whom the health insurance company has concluded a contract on dispensing pursuant to the act governing the public health insurance.

(5) The information systems used by the prescriber for the purposes of prescribing and by the dispensing individual for the purposes of dispensing of devices must be fully compatible with the ePrescription system and with its operating documentation.

(6) Data available to the prescribers and dispensing individuals via the ePrescription system may be used solely for the purposes of prescribing and dispensing of devices.

(7) The implementing legal regulation stipulates:

a) the procedure and conditions for the provision of identification data as per paragraph (3)(b); and

b) the method of providing the identification data referred to under paragraph (4).

TITLE II

DISPENSING OF DEVICES

Section 32

Conditions governing the dispensing of devices

(1) Devices shall be dispensed on the basis of an electronic order or paper order. Dispensing shall include the provision of information necessary for the correct and safe use of the dispensed device.

(2) During dispensing on the basis of an electronic order, the dispensing individual must forthwith inform the central electronic order repository via the ePrescription system that the prescribed device has been dispensed.

(3) Devices may be dispensed by dispensing persons only. A dispensing person shall mean the provider of healthcare services of pharmaceutical care, an operator of an optician's outlet or a person with whom the health insurance company has concluded a contract on dispensing pursuant to the act governing public health insurance. The person with whom the health insurance company has concluded a contract on dispensing pursuant to the act governing public health insurance may only dispense a device for which the contract on dispensing has been concluded.

(4) A device, except for a risk class I medical device, may be dispensed in a pharmacy or in a dispensary of devices solely by

a) a pharmacist of the relevant professional competence;

b) a pharmaceutical assistant of the relevant professional competence; or

c) an orthotist-prosthetist qualified to perform the profession without expert supervision or an orthopaedic prosthetist where dispensing of an orthotic-prosthetic device is concerned.

(5) An eye-correction device[13)] may be dispensed in an optician's outlet only. Such device may be dispensed only by

a) an optometrist;

b) a licensed eye optician or licensed eye technician;

c) an eye optician or eye technician; or

d) an ophthalmologist.

Section 33

Mail-delivery device dispensing

(1) Mail-delivery dispensing shall mean dispensing of a device on the basis of a paper or electronic order by mail delivery. The offering of devices for the purposes of mail-delivery dispensing and the receipt of orders from persons for the conduct of mail-delivery dispensing is considered part of mail-delivery dispensing. Mail-delivery dispensing must meet the requirements governing sale via information society services stipulated by the Medical Device Regulation or by the In Vitro Diagnostic

Medical Device Regulation.

(2) Where devices referred to under Section 28(3) are concerned, mail-delivery dispensing is prohibited.

Section 34

Obligations of the person providing for mail-delivery dispensing of devices

In mail-delivery dispensing of devices, the dispensing person shall be obliged to

a) arrange for the publication of information about mail-delivery dispensing, offer of the device, its price, the timeline within which it is possible to send the device to the ordering party, and the costs associated with mail-delivery dispensing on its website; a mere publication of the offer shall not be considered advertising pursuant to the act governing advertising regulation[14)];

b) make sure that the person conducting the dispensing of the device meets the requirements set forth by Section 32(4) and (5);

c) provide for packaging and transportation; the dispensing person shall be responsible for maintaining the quality of the devices, even in cases where it contracts transportation of the device with another person;

d) make sure that the shipments are sent to the ordering party no later than within the timeline published as per letter (a) or that the ordering party is forthwith informed by the dispensing person about reasons for which delivery cannot be carried out or that it will be carried out at a later delivery date, including information about the duration of such delivery period; and

e) arrange for an information service provided by the dispensing person pursuant to Section 32(3) or by the authorised person pursuant to Section 32(4) and (5) during defined working hours; this information service shall also serve for the collection and hand-over of information about arising incidents.

Section 35

Device replacement

(1) During dispensing of a device prescribed on electronic or paper order, the dispensing person shall inform the patient about possible alternatives thereto and, upon the patient’s consent, may replace it with another device which is replaceable with the prescribed device in terms of performance and intended purpose. The dispensing individual shall note the replacement made on the order.

(2) Where the paper order bears the note “Replacement not allowed” or the electronic order has an active “No replacement” flag, the dispensing person may dispense only the prescribed device.

Section 36

Order excerpt

Where the dispensing individual does not have the full quantity of the device required by the prescription at the time of dispensing the device on paper order, he/she shall issue an excerpt of the order for the missing device which shall bear the word “Excerpt”. The excerpt of the paper order shall contain data from the original paper order and information on the scope of the previously completed dispensing. The original paper order shall be marked with the words “excerpt made” and with information on the scope of the completed dispensing. The period for which the excerpt of the paper order may be used shall be governed by Section 28(5) analogously.

Section 37

Obligations of dispensing persons

The dispensing person shall be obliged to

a) observe good storage practice;

b) provide the patient with the complete information about facts that may affect the patient's safety and health in association with the use of the device being dispensed;

c) store all paper orders and request forms for dispensed devices referred to under Section 28(3) for the period of five years, unless the device was reimbursed from public health insurance;

d) take out devices that cannot be used pursuant to Section 38(1) and store them separately.

PART SEVEN

USE OF DEVICES

Section 38

General provision

(1) A device may not be used if it is a device

a) that has been placed onto the market contrary to the Medical Device Regulation where medical devices are concerned or contrary to the In Vitro Diagnostic Medical Device Regulation where in vitro diagnostic medical devices are concerned and the person who uses such device was or should and could be aware of this fact;

b) which is reasonably suspected to jeopardise the safety and health of patients or third persons, even if the device has been properly installed or inserted into the human body, maintained and used in compliance with its intended purpose[6)];

c) whose time limit for using or implanting the device safely has expired[15)];

d) which has shortcomings in terms of its manufacture that may result in a jeopardy to the health of patients or third persons; or

e) whose safety may be jeopardised or performance affected due to an obviously compromised integrity of the original packaging.

(2) Only medical devices meeting the requirements set forth by the Medical Device Regulation and in vitro diagnostic medical devices meeting the requirements of the In Vitro Diagnostic Medical Device Regulation may be used in the provision of healthcare services.

(3) Where the healthcare provider manufactures and uses a medical device within the scope of healthcare services provided thereby in compliance with Art. 5(5) of the Medical Device Regulation or manufactures and uses an in vitro diagnostic medical device in compliance with Art. 5(5) of the In Vitro Diagnostic Medical Device Regulation, it shall be obliged to provide information about such device upon the Institute's request.

Section 39

Obligations of healthcare provider in the use of devices

(1) The healthcare provider shall be obliged to ensure that

a) the device is used in compliance with the manufacturer's instructions;

b) a device with measuring function is operated in compliance with the requirements stipulated by

another legal regulation governing the sphere of metrology;

c) the person providing healthcare services is instructed about the necessity to make sure, prior to each use of the device, that the device is in proper technical condition, functional, and may be safely used, where such device check is practicable; this requirement shall adequately apply also to the accessories, software, and another product which is expected to interact with the device in question;

d) good storage practice is observed;

e) the device is serviced in compliance herewith;

f) in case the manufacturer provided the healthcare provider with a custom-made medical device for use in the provision of healthcare services for a specific patient, the healthcare provider provided this patient with the manufacturer's statement for the custom-made medical device referred to under Annex XIII(1) of the Medical Device Regulation, which was attached by the manufacturer to this medical device; and

g) a field safety corrective action determined by the manufacturer in order to eliminate the risks of a serious incident associated with the device supplied onto the market has been implemented.

(2) The healthcare provider must not use the device in the provision of healthcare services where cases listed under Section 38(1) are concerned. Furthermore, the healthcare provider must not use the device in the provision of healthcare services in case the instructions for use in the Czech language are not available thereto; this shall not apply to risk class I or IIa medical devices or to those in vitro diagnostic medical devices for which the manufacturer determined that the safe use of the device does not require instructions for use.

(3) Where a risk class IIb or III medical device is used in the provision of healthcare services, the healthcare provider shall be obliged to make a record of such use in the medical documentation kept for the patient.

(4) The healthcare provider shall be obliged to keep unique identification of devices, except for risk class I medical devices and risk class A in vitro diagnostic medical devices supplied thereto. Healthcare providerHealthcare providers shall be obliged to present this information to the Institute upon request of the latter.

(5) The healthcare provider shall be obliged to keep documentation of the used devices

a) for which training must be conducted;

b) for which a safety technical control must be carried out; or

c) which have been determined to be legal working measuring instruments by a legal regulation governing the sphere of metrology[16)].

(6) The content of the documentation of used devices referred to under paragraph (5) is stipulated by an implementing legal regulation.

Section 40

Device information

(1) The healthcare provider shall be obliged to ensure that the complete information from the instructions for use in the Czech language is available to the person providing healthcare services by means of the device; the obligation to arrange of the availability of the instructions for use shall not apply to risk class I or IIa medical devices or to in vitro diagnostic medical devices in respect of which the manufacturer determined that the safe use of the device does not require such instructions for use.

(2) The healthcare provider who has implanted an implantable device shall be obliged to provably provide the patient who has been implanted this medical device or to his/her legal guardian

or carer with the implant card that shall specify the identity of the patient and information referred to under Article 18 of the Medical Device Regulation in any provable manner that will allow the patient ready access to the concerned information. The information must be in the Czech language.

(3) The obligation stipulated by paragraph (2) shall not apply to medical devices referred to under Art. 18(3) of the Medical Device Regulation.

Section 41

Training

(1) The healthcare provider shall be obliged to ensure that the device in respect of which the manufacturer determined so in the instructions for use be used or operated in the provision of healthcare services solely by a person who

a) has been trained in the use of the device in a manner compliant with the respective instructions for use; and

b) has been acquainted with the risks associated with the use of the concerned device.

(2) The training referred to under paragraph (1)(a) may be conducted only by

a) the manufacturer or a person authorised thereby;

b) a person who has been trained by a person who has been authorised by the manufacturer for the conduct of such trainings; or

c) a person who has been trained by a person referred to under letter (a) or (b) and has at least two years of practical experience in the use of the device in question, unless the manufacturer stipulates otherwise.

(3) The healthcare provider shall be obliged to keep and store information about all completed trainings. The healthcare provider shall be obliged to store this information for the entire period the device is in use and for the period of one year after decommissioning of the device.

(4) In case of training referred to under paragraph (2), for a device whose manufacturer ceased to exist it is possible to replace the advice to be provided by the manufacturer with an advice by a person who has at least three years of practical experience in the use of the concerned device type.

Special use of a device

Section 42

(1) In case of a jeopardy to the patient’s life or health, the physician providing healthcare services may use a device in a manner which is not consistent with its instructions for use, if there is no other device of the required characteristics available thereto, providing such use has been clinically verified for a similar device type.

(2) Where the physician intends to use a device in a manner described in paragraph (1), he/she shall inform the patient or, where applicable, his/her legal guardian or carer, about this fact and about potential consequences and risks of this procedure. Where such provision of information is not possible due to the patient’s condition of health or due to the absence of the patient’s legal guardian or carer, the physician shall do so as soon as permissible with regard to the patient’s condition of health or the presence of the patient’s legal guardian or carer.

(3) The physician shall make a record of the procedure taken as per paragraph (1), the reasons leading thereto, and of the provision of information pursuant to paragraph (2) in the medical documentation kept for the patient.

Section 43

(1) Where a military healthcare provider referred to under the Act on Professional Soldiers[17)] or, where applicable, another healthcare provider provides, within the territory of the Czech Republic, on the basis of a contract on the provision of healthcare services to professional soldiers concluded with the health insurance company specified by the Act on Public Health Insurance, healthcare services to soldiers on active duty at the time of war or a state of emergency using devices, they may divert from this Act.

(2) Where a military healthcare provider referred to under the Act on professional Soldiers[17)] provides healthcare services using devices to soldiers on active duty appointed to fulfil the tasks of the armed forces of the Czech Republic or the Military Police outside the territory of the Czech Republic[18)], they may divert from this Act.

PART EIGHT

DEVICE SERVICING

Section 44

General provision

(1) Servicing shall mean the conduct of safety technical controls and repairs of the device in compliance with the manufacturer's instructions, this Act, and other legal regulations. Repair and safety technical control of a custom-made device shall not be considered servicing hereunder.

(2) A device, except for risk class I medical devices and risk class A in vitro diagnostic medical devices may be serviced solely by a notified person; this shall not apply to the procedure outlined under paragraph (3). Where a device with a measuring function is concerned, it must be serviced in compliance with another legal regulation governing the sphere of metrology.

(3) Where the manufacturer has explicitly determined that the device may be serviced solely by a person authorised thereby who does not operate within the territory of the Czech Republic, the requirements stipulated by Section 45(4) and (5) and Section 46(2) and (3) shall not apply to the person authorised as explained above.

(4) The healthcare provider shall be obliged to keep the documentation about completed servicing as per paragraph (3) in the Czech, Slovak or English language for the entire period the device is in use, as well as for the period of one year after its decommissioning.

(5) Any natural or legal person supplying a part intended as a replacement of an identical or similar integral part of a device as per Art. 23(1) of the Medical Device Regulation or Art. 20(1) of the In Vitro Diagnostic Medical Device Regulation onto the market within the territory of the Czech Republic shall be obliged to keep the supporting documentation for the period of at least ten years of the date of supply of the last such part onto the market, and present it upon the Institute's request.

Section 45

Safety technical control of devices

(1) A safety technical control shall mean the conduct of regular acts performed to maintain the safety and full performance of the device.

(2) A safety technical control shall, moreover, include the conduct of an electrical check of a device, which is an electrical apparatus. For the purposes hereof, an electrical apparatus shall mean an apparatus that may jeopardise one's life, health or property with electric current. An electrical check of the device shall be conducted in a manner stipulated by the manufacturer; where no such procedure has been stipulated by the manufacturer, the procedure described in a technical standard governing electrical medical equipment or electrical apparatuses that are in vitro diagnostic medical

devices shall be used[19)].

(3) A safety technical control shall be performed for a device with regard to its classification into the risk class and within the scope and frequency established by the manufacturer. Where the manufacturer does not stipulate the frequency of safety technical controls for a device that is an electrical apparatus, the safety technical controls shall be performed at least on a bi-annual basis. The safety technical control must be performed no later than in the calendar month during which the timeline for its conduct will expire, unless the manufacturer stipulates otherwise.

(4) The servicing person who performs the safety technical control, shall be obliged to

a) provably ensure that all staff conducting safety technical controls completed an up-to-date training in the area of servicing conducted by the person referred to under Section 41(2)(a) or (b) within the scope prescribed by the manufacturer;

b) ensure that safety technical controls of active risk class IIa medical devices, risk class IIb and III medical devices, and in vitro diagnostic medical devices be conducted solely by
1. an employee with professional competence to perform the profession of a biomedical technician, biomedical engineer or orthotist-prosthetist;
2. an employee who has completed a bachelor's or master's degree in the area of education in machinery, technologies and materials, or electrotechnics or similar university education obtained through studies at a university not included in an area of education[20)] and at least three months of professional practical experience in the area of safety technical controls of devices;
3. an employee who has completed secondary education in a field of technology, concluded with a general certificate of education or higher specialised education in a field of technology and at least six months of professional practical experience in the area of safety technical controls of devices;
4. an employee who has completed secondary education concluded with a general certificate of education and at least one year of professional practical experience in the area of safety technical controls of devices; or
5. an employee who has completed a bachelor's or master's degree in the area of education in machinery, technologies and materials, or electrotechnics or similar university education obtained through studies at a university not included in an area of education[20)] or who has completed secondary education concluded with a general certificate of education or higher specialised education in a field of technology under a direct supervision by a person referred to under indents (1) to (4); the conduct of these safety technical controls of devices shall be considered practical experience for the purposes of indents (2) to (4);

c) where a safety technical control of a device that is an electrical apparatus is concerned, ensure that along with the requirements stipulated under letters (a) and (b), the employees conducting this safety technical control also meet the requirements for
1. staff carrying out independent activities pursuant to another legal regulation governing the professional competence in the field of electrotechnics; or
2. staff cognisant as per another legal regulation governing professional competence in the field of electrotechnics under supervision by a person referred to under indent (1); and

d) provide for adequate material and technical equipment for the conduct of safety technical controls.

(5) Following the completion of a safety technical control, the servicing person must make sure that the employee conducting the safety technical control made a record about such control and signed it. Where the safety technical control is conducted by a person referred to under paragraph (4)(b)(5), the record shall be signed also by the person acting as the direct supervisor. The healthcare provider shall be obliged to keep this record for the entire period the device is in use and, moreover, for the period of one year after the decommissioning of the device.

(6) Unless the manufacturer stipulates otherwise, the requirements governing the staff conducting safety technical controls shall not apply to safety technical controls performed for a risk class I device without measuring function which is not an electrical apparatus.

(7) In case of a safety technical control of a device whose manufacturer ceased to exist, it shall be possible to replace the training referred to under paragraph (4)(a) with training provided by a

person with at least five years of practical experience in servicing the device type in question.

Section 46

Device repair

(1) A repair shall mean a set of acts through which a damaged device is returned to original or operable and safe condition without changing its technical parameters or intended purpose.

(2) The servicing person who conducts the repair shall be obliged to

a) provably ensure that all staff conducting the repair completed an up-to-date training in the area of repairing the relevant device conducted by a person referred to under Section 41(2)(a) or (b) within the scope prescribed by the manufacturer;

b) ensure that the repair of an active risk class IIa medical device, risk class IIb and III medical device or in vitro diagnostic medical device be conducted solely by
1. an employee with professional competence to perform the profession of a biomedical technician, biomedical engineer or orthotist-prosthetist;
2. an employee who has completed a bachelor's or master's degree in the area of education in machinery, technologies and materials, or electrotechnics or similar university education obtained through studies at a university not included in an area of education[20)] and at least three months of professional practical experience in the area of device repairs;
3. an employee who has completed secondary education in a field of technology concluded with a general certificate of education or higher specialised education in a field of technology and at least six months of professional practical experience in the area of device repairs;
4. an employee who has completed secondary education concluded with a general certificate of education and at least one year of professional practical experience in the area of device repairs; or
5. an employee who has completed a bachelor's or master's degree in the area of education in machinery, technologies and materials, or electrotechnics or similar university education obtained through studies at a university not included in an area of education[20)] or who has completed secondary education concluded with a general certificate of education or higher specialised education in a field of technology under a direct supervision by a person referred to under indents (1) to (4); the conduct of these repairs of devices shall be considered practical experience for the purposes of indents (2) to (4);

c) where a repair of a device that is an electrical apparatus is concerned, ensure that along with the requirements stipulated under letters (a) and (b), the employees conducting this repair also meet the requirements for
1. staff carrying out independent activities pursuant to another legal regulation governing the professional competence in the field of electrotechnics; or
2. staff cognisant as per another legal regulation governing professional competence in the field of electrotechnics under supervision by a person referred to under indent (1);

d) where a repair of a device containing a pressure apparatus is concerned, ensure that the repair of the pressure apparatus is conducted by staff who meet the requirements for professional competence for pressure apparatus repairs set forth by another legal regulation;

e) where a repair of a device containing a gas apparatus is concerned, ensure that the repair of the gas apparatus is conducted by staff who meet the requirements for professional competence for gas apparatus repairs set forth by another legal regulation; and

f) provide for adequate material and technical equipment for the conduct of repairs.

(3) Following the completion of the repair, the servicing person must make sure that the employee conducting the repair retested the safety and performance of the device and made a record of the repair and retesting and signed it. Where the repair is conducted by a person referred to under paragraph (2)(b)(5), the record shall be signed also by the person acting as the direct supervisor. The healthcare provider shall be obliged to keep this record for the entire period the device is in use and, moreover, for the period of one year after the decommissioning of the device.

(4) Unless the manufacturer stipulates otherwise, the requirements governing the staff conducting repairs shall not apply to repairs performed in a risk class I device without measuring function which is not an electrical apparatus.

(5) In case of a repair of a device whose manufacturer ceased to exist, it shall be possible to replace the training referred to under paragraph (2)(a) with training provided by a person with at least five years of practical experience in servicing the device type in question.

Section 47

Device inspection

(1) Devices that are firmly connected to an electrical power supply and devices that contain pressure, gas or lifting apparatuses, shall be subjected to inspections along with their servicing.

(2) An inspection referred to under paragraph (1) shall mean an electrical inspection, pressure inspection, gas inspection, or lifting inspection pursuant to other legal regulations.

PART NINE

VIGILANCE, MARKET SURVEILLANCE, AND CONTROL

TITLE I

VIGILANCE

Section 48

Trend reporting within the scope of vigilance

The Institute assesses trend reporting for medical devices pursuant to Art. 88(1) of the Medical Device Regulation and for in vitro diagnostic medical devices pursuant to Art. 83(1) of the In Vitro Diagnostic Medical Device Regulation. Where the outcome of the assessment indicates a risk for the safety of patients, users or other natural persons or a risk for public health, the Institute shall invite the manufacturer in writing to adopt appropriate measures in order to safeguard the protection of public health and the safety of patients, users or other natural persons, and shall communicate the outcome of the assessment and the adopted measures to the Commission, other competent authorities, and the notified body who issued the certificate of conformity pursuant to Article 56 of the Medical Device Regulation or pursuant to Article 51 of the In Vitro Diagnostic Medical Device Regulation.

Section 49

Serious incident record-keeping and field safety corrective actions

(1) The Institute shall keep the entire information concerning a serious incident occurring within the territory of the Czech Republic or a field safety corrective action which has been or is to be implemented within the territory of the Czech Republic and which was reported to the Institute for medical devices in compliance with the Medical Device Regulation or, for in vitro diagnostic medical devices, in compliance with the In Vitro Diagnostic Medical Device Regulation, for the period of 15 years; in case of a serious incident associated with an injury to the health of the user, patient or another natural person or death thereof that occurred within the territory of the Czech Republic, the Institute shall keep any and all information regarding this serious indecent that has been reported thereto for the period of 30 years.

(2) The Institute shall store reports of suspected serious incidents received from device users for the period of ten years.

(3) The Institute shall assess any and all information reported thereto in compliance with

Article 87 of the Medical Device Regulation or in compliance with Article 82 of the In Vitro Diagnostic Medical Device Regulation and pertaining to a serious incident that occurred within the territory of the Czech Republic or a field safety corrective action which has been or is to be implemented within the territory of the Czech Republic together with the manufacturer and, if applicable, with the concerned notified body.

(4) As soon as the Institute receives the final report on the outcome of investigations into a serious incident, it shall review this report with a view to safeguarding the safety and health of the users, patients, and other natural persons.

(5) The Institute has the right to request any documents necessary for risk assessment. Should the Institute find out that the field safety corrective actions adopted by the manufacturer are inadequate, following consultation with the manufacturer, the Institute shall adopt measures necessary to safeguard the safety and health of the users, patients, and other natural persons and to minimise the potential for the serious incident to recur.

(6) Via the Medical Device Information System, the Institute shall publish field safety notices sent by the manufacturer, authorised representative or distributor to the users in relation to a field safety corrective action which has been or is to be implemented within the territory of the Czech Republic.

Section 50

Obligations of healthcare provider in the sphere of vigilance

(1) Where a serious incident occurs or is suspected, the healthcare provider shall be obliged to

a) implement any necessary measures in order to minimise the negative consequences of the incident that has occurred;

b) provide the manufacturer and the Institute with access to the concerned device and any documentation for the purposes of inspection and determination of the cause of the incident that has occurred; and

c) provide the manufacturer and the Institute with any cooperation and information necessary to establish the cause of the incident that has occurred.

(2) A healthcare provider suspecting that a serious incident resulting in an injury to the patient’s health or his/her death has occurred shall be obliged to record this fact in the healthcare documentation kept for the patient.

TITLE II

MARKET SURVEILLANCE AND CONTROL

Section 51

Conduct of control

(1) Control over compliance with the obligations stipulated hereby and by directly applicable regulations of the European Union governing the area of devices shall be conducted by the Institute.

(2) The authorisation to conduct control shall have the form of an identification card. The identification card shall be issued by the Institute. Specimen identification card is provided by the implementing legal regulation.

Section 52

Preventive actions

The Institute shall issue decisions on actions referred to under Article 98 of the Medical Device Regulation or under Article 93 of the In Vitro Diagnostic Medical Device Regulation. Appeal from such decision has no suspensory effect.

Section 53

Measures

(1) Where the procedure outlined by Art. 95(4), Art. 95(7) or Art. 97(2) of the Medical Device Regulation is used or where the procedure outlined by Art. 90(4), Art. 90(7) or Art. 92(2) of the In Vitro Diagnostic Medical Device Regulation is used, the Institute shall forthwith adopt appropriate restrictive or prohibitive measures adequate to the nature of the risk of making such device available on the market. Such measures shall be:

a) limiting the use and availability of the device on the market by way adequate to the nature of the risk;

b) withdrawing the device from the market;

c) recalling the device;

d) terminating the use of the device.

(2) The Institute shall issue decisions on the measures referred to under paragraph (1). Appeal from such decision has no suspensory effect.

(3) Where an implementing regulation through which the Commission, employing the procedure stipulated by Art. 96(1) of the Medical Device Regulation or by Art. 91(1) of the In Vitro Diagnostic Medical Device Regulation decides on insubstantiality of such measure after the decision on the adoption of the measure referred to under paragraph (1) becomes final, the Ministry shall cancel the measure without unnecessary delay. The decision on the cancellation of the measure shall be issued as the first act in a procedure initiated ex officio and no appeal therefrom shall be permissible.

PART TEN

OFFENCES

Section 54

General offences

(1) An offence is committed by anyone who

a) contrary to Section 9, reprocesses a single-use device or places a reprocessed single-use device on the market within the Czech Republic or makes it available on the market within the Czech Republic or uses such device;

b) breaches the prohibition stipulated by Section 26(1);

c) dispenses a device without being a person authorised to dispense the device pursuant to Section 32(3) to (5);

d) contrary to Art. 5(1) of the Medical Device Regulation or contrary to Art. 5(1) of the In Vitro Diagnostic Medical Device Regulation places on the market or puts into service a device which does not meet the requirements of the Medical Device Regulation or of the In Vitro Diagnostic Medical Device Regulation or of the Commission implementing regulation issued on the basis of Art. 5(6) of

the Medical Device Regulation or Commission implementing regulation issued on the basis of Art. 5(6) of the In Vitro Diagnostic Medical Device Regulation, or a device referred to under Art. 5(5) of the Medical Device Regulation or under Art. 5(5) of the In Vitro Diagnostic Medical Device Regulation, which does not meet the general requirements for safety and performance stipulated by Annex I to the Medical Device Regulation or does not meet the general requirements for safety and performance stipulated by Annex I to the In Vitro Diagnostic Medical Device Regulation;

e) contrary to Art. 6(1) of the Medical Device Regulation or contrary to Art. 6(1) of the In Vitro Diagnostic Medical Device Regulation, offers via information society services a device which does not meet the requirements stipulated by the Medical Device Regulation or by the In Vitro Diagnostic Medical Device Regulation;

f) contrary to Art. 6(2) of the Medical Device Regulation or contrary to Art. 6(2) of the In Vitro Diagnostic Medical Device Regulation, uses a device, which has not been placed on the market, within the scope of business operation for the provision of a diagnostic or therapeutic service offered via information society services or other means of communication directly or via agents to a natural or legal person established within the territory of a Member State, and this device does not meet the requirements of the Medical Device Regulation or In Vitro Diagnostic Medical Device Regulation;

g) operates contrary to a decision of the Institute issued pursuant to Section 5(3);

h) contrary to Art. 6(3) of the Medical Device Regulation or contrary to Art. 6(3) of the In Vitro Diagnostic Medical Device Regulation, fails to submit the declaration of conformity for the device to the Institute;

i) in device labelling, provision of instructions for use of the devices, making devices available on the market or putting devices into service or in advertising for such devices fails to proceed in compliance with Article 7 of the Medical Device Regulation or in compliance with Article 7 of the In Vitro Diagnostic Medical Device Regulation;

j) fails to meet any of the obligations imposed upon the manufacturer in the conduct of activities referred to under Art. 16(1) of the Medical Device Regulation or under Art. 16(1) of the In Vitro Diagnostic Medical Device Regulation;

k) places on the market a system or procedure pack without meeting the requirements stipulated by Article 22 of the Medical Device Regulation;

l) makes available on the market a part referred to under Art. 23(1) of the Medical Device Regulation or under Art. 20(1) of the In Vitro Diagnostic Medical Device Regulation, not making sure that the concerned part does not adversely affect the device safety or performance, or fails to keep support documentation in compliance with Art. 23(1) of the Medical Device Regulation or in compliance with Art. 20(1) of the In Vitro Diagnostic Medical Device Regulation;

m) as a person responsible for placing a medical device system or procedure pack on the market, fails to proceed in compliance with Art. 29(2) of the Medical Device Regulation;

n) prescribes a device without being a person authorised therefor pursuant to Section 28(1) to (3); or

o) fails to proceed in compliance with Commission measures adopted in compliance with Art. 96(3) of the Medical Device Regulation or in compliance with Art. 91(3) of the In Vitro Diagnostic Medical Device Regulation.

(2) For the commitment of an offence, a fine may be imposed up to the amount of

a) 500,000 CZK, where an offence referred to under paragraph (1)(h) is concerned;

b) 2,000,000 CZK, where an offence referred to under paragraph (1)(c), (g) or (n) is concerned;

c) 5,000,000 CZK, where an offence referred to under paragraph (1)(a), (b), (j) or (m) is concerned;

d) 15,000,000 CZK, where an offence referred to under paragraph (1)(i) or (o) is concerned; or

e) 30,000,000 CZK, where an offence referred to under paragraph (1)(d), (e), (f), (k) or (l) is concerned.

Section 55

Offences in the area of manufacture

(1) The manufacturer of a device commits an offence by

a) failing, as the manufacturer referred to under Annex XVI to the Medical Device Regulation, to meet the common specifications for these products contrary to Art. 9(4) of the Medical Device Regulation;

b) failing, contrary to Art. 10(1) of the Medical Device Regulation or contrary to Art. 10(1) of the In Vitro Diagnostic Medical Device Regulation, to ensure that in placing devices on the market or putting them into service, these devices were manufactured in compliance with the Medical Device Regulation or with the In Vitro Diagnostic Medical Device Regulation;

c) failing to establish, document, apply or maintain a risk management system pursuant to Art. 10(2) of the Medical Device Regulation or pursuant to Art. 10(2) of the In Vitro Diagnostic Medical Device Regulation;

d) failing to conduct a clinical evaluation or performance evaluation or to update such evaluation or its documentation in compliance with Art. 10(3) of the Medical Device Regulation or in compliance with Art. 10(3) of the In Vitro Diagnostic Medical Device Regulation;

e) failing to draw up technical documentation of devices in compliance with Art. 10(4) of the Medical Device Regulation or in compliance with Art. 10(4) of the In Vitro Diagnostic Medical Device Regulation;

f) failing to update the technical documentation of devices on an ongoing basis in compliance with Art. 10(4) of the Medical Device Regulation or in compliance with Art. 10(4) of the In Vitro Diagnostic Medical Device Regulation;

g) failing to draw up declaration of conformity or failing to place the CE mark on the device in compliance with Art. 10(6) of the Medical Device Regulation or in compliance with Art. 10(5) of the In Vitro Diagnostic Medical Device Regulation;

h) failing to keep the technical documentation, the EU declaration of conformity or a copy of relevant certificates of conformity, including any changes and attachments, in compliance with Art. 10(8) of the Medical Device Regulation or in compliance with Art. 10(7) of the In Vitro Diagnostic Medical Device Regulation;

i) failing, contrary to Art. 10(8) of the Medical Device Regulation or contrary to Art. 10(7) of the In Vitro Diagnostic Medical Device Regulation, to provide the complete technical documentation or a summary thereof to the Institute upon request thereof;

j) failing to ensure, if it is not established within the territory of a Member State, that documentation necessary for the fulfilment of tasks stipulated by Art. 11(3) of the Medical Device Regulation or by Art. 11(3) of the In Vitro Diagnostic Medical Device Regulation is available to its authorised representative at all times;

k) failing to establish, document, apply, maintain, keep up to date, and continuously improve a quality management system so that this system were compliant with the requirements stipulated by Art. 10(9) of the Medical Device Regulation or compliant with the requirements stipulated by Art. 10(8) of the In Vitro Diagnostic Medical Device Regulation;

l) failing to apply or keep up to date a post-market surveillance system in compliance with Art. 10(10) of the Medical Device Regulation or in compliance with Art. 10(9) of the In Vitro Diagnostic Medical

Device Regulation;

m) failing to ensure that information referred to under Art. 10(11) or Art. 32(1) of the Medical Device Regulation or under Art. 10(10) or Article 29 of the In Vitro Diagnostic Medical Device Regulation is attached to the device;

n) failing to meet any of the obligations stipulated by Art. 10(12) of the Medical Device Regulation or by Art. 10(11) of the In Vitro Diagnostic Medical Device Regulation;

o) failing to have a system for recording and reporting of incidents and field safety actions in compliance with Art. 10(13) of the Medical Device Regulation or in compliance with Art. 10(12) of the In Vitro Diagnostic Medical Device Regulation;

p) failing to submit to the Institute upon request thereof the complete information and documentation necessary to evidence device conformity pursuant to Art. 10(14) of the Medical Device Regulation or pursuant to Art. 10(13) of the In Vitro Diagnostic Medical Device Regulation or contrary to Art. 10(14) of the Medical Device Regulation or contrary to Art. 10(13) of the In Vitro Diagnostic Medical Device Regulation, failing to provide a requested free sample of the device or failing to provide access to the concerned device or failing to provide required cooperation;

q) where it outsources the design or manufacture of its devices with another legal or natural person, failing to provide the information about the identity of such person in compliance with Art. 10(15) or Art. 20(3) or (5) of the Medical Device Regulation or in compliance with Art. 10(14) or Art. 18(3) or (5) of the In Vitro Diagnostic Medical Device Regulation;

r) contrary to Art. 10(16), subparagraph two of the Medical Device Regulation or contrary to Art. 10(15), subparagraph two of the In Vitro Diagnostic Medical Device Regulation, failing to adopt, in a manner corresponding to the risk class, device type and size of the enterprise, measures allowing for sufficient financial coverage in terms of liability referred to by Council Directive 85/374/EEC[21)];

s) placing, as a manufacturer who is not established in a Member State, a device on the market without having appointed an authorised representative in compliance with Article 11 of the Medical Device Regulation or in compliance with Article 11 of the In Vitro Diagnostic Medical Device Regulation;

t) concluding an agreement with the authorised representative without specifying a clearly defined detailed procedure for the change of the authorised representative in this agreement, or specifying the procedure, but without reflecting aspects referred to under Article 12 of the Medical Device Regulation or under Article 12 of the In Vitro Diagnostic Medical Device Regulation;

u) not having a person responsible for regulatory compliance as referred to under Art. 15(1) of the Medical Device Regulation or under Art. 15(1) of the In Vitro Diagnostic Medical Device Regulation;

v) failing to provide the information stipulated by Art. 18(1) of the Medical Device Regulation for an implantable medical device;

w) failing to update or keep a declaration of conformity in the Czech, Slovak or English language in compliance with Article 19 of the Medical Device Regulation or in compliance with Article 17 of the In Vitro Diagnostic Medical Device Regulation;

x) not being able to identify the operator in compliance with Art. 25(2) of the Medical Device Regulation or in compliance with Art. 22(2) of the In Vitro Diagnostic Medical Device Regulation;

y) failing to meet any of the obligations associated with the UDI system pursuant to Article 27 of the Medical Device Regulation or pursuant to Article 24 of the In Vitro Diagnostic Medical Device Regulation or any of the registration obligations set forth by Article 29 of the Medical Device Regulation or by Article 26 of the In Vitro Diagnostic Medical Device Regulation; or

z) failing to enter the data stipulated by Art. 31(1) of the Medical Device Regulation or by Art. 28(1) of the In Vitro Diagnostic Medical Device Regulation to the electronic system for the purposes of

registration.

(2) The manufacturer of a device commits an offence, moreover,

a) by failing to draw up a rationale in case of procedure outlined under Art. 61(10) of the Medical Device Regulation or contrary to Art. 56(4) of the In Vitro Diagnostic Medical Device Regulation in compliance with this article;

b) if its post-market surveillance system referred to under Article 83 of the Medical Device Regulation or under Article 78 of the In Vitro Diagnostic Medical Device Regulation is not based on the post-market surveillance plan or this plan is not in compliance with the requirements stipulated by Annex III(1.1) to the Medical Device Regulation or by Annex III(1.1) to the In Vitro Diagnostic Medical Device Regulation or this plan is not in compliance with the requirements stipulated by Art. 88(1), subparagraph two of the Medical Device Regulation or by Art. 83(1), subparagraph two of the In Vitro Diagnostic Medical Device Regulation;

c) by not having a post-market surveillance plan for devices, except for custom-made devices, as part of the technical documentation referred to under Annex III to the Medical Device Regulation or under Annex III to the In Vitro Diagnostic Medical Device Regulation;

d) by failing to implement preventive or corrective actions or failing to meet the information duty pursuant to Art. 83(4) of the Medical Device Regulation or pursuant to Art. 78(4) of the In Vitro Diagnostic Medical Device Regulation;

e) by failing to draw up, update or provide, upon request, access for the Institute to the post-market surveillance report for risk class I medical devices in compliance with Article 85 of the Medical Device Regulation or by failing to draw up, update or provide, upon request, access for the Institute to the post-market surveillance report for risk class A and B in vitro diagnostic medical devices in compliance with Article 80 of the In Vitro Diagnostic Medical Device Regulation;

f) by failing to draw up, update or submit a safety report referred to by Article 86 of the Medical Device Regulation or in by Article 81 of the In Vitro Diagnostic Medical Device Regulation;

g) by failing to report a serious incident in compliance with Art. 87(1)(a) of the Medical Device Regulation or in compliance with Art. 82(1)(a) of the In Vitro Diagnostic Medical Device Regulation or by failing to proceed in compliance with Art. 87(11) of the Medical Device Regulation or in compliance with Art. 82(11) of the In Vitro Diagnostic Medical Device Regulation;

h) by failing to report a safety corrective action in compliance with Art. 87(1)(b) of the Medical Device Regulation or in compliance with Art. 82(1)(b) of the In Vitro Diagnostic Medical Device Regulation or by failing to proceed in compliance with Art. 87(8) of the Medical Device Regulation or in compliance with Art. 82(8) of the In Vitro Diagnostic Medical Device Regulation;

i) by failing to report a serious incident in compliance with Art. 87(3), (4) or (5) of the Medical Device Regulation or in compliance with Art. 82(3),(4) or (5) of the In Vitro Diagnostic Medical Device Regulation;

j) by failing to report an incident in compliance with Art. 87(7) of the Medical Device Regulation or in compliance with Art. 82(7) of the In Vitro Diagnostic Medical Device Regulation;

k) by failing to report a trend in compliance with Art. 88(1) of the Medical Device Regulation or in compliance with Art. 83(1) of the In Vitro Diagnostic Medical Device Regulation;

l) by failing to carry out investigation into a serious incident in compliance with Art. 89(1) of the Medical Device Regulation or in compliance with Art. 84(1) of the In Vitro Diagnostic Medical Device Regulation;

m) by failing to provide the Institute upon request thereof with documentation for the purposes of risk assessment in compliance with Art. 89(3) of the Medical Device Regulation or in compliance with Art. 84(3) of the In Vitro Diagnostic Medical Device Regulation or by failing to provide the Institute with a

final report in compliance with Art. 89(5) of the Medical Device Regulation or in compliance with Art. 84(5) of the In Vitro Diagnostic Medical Device Regulation;

n) by failing to take the course of action regarding a safety notice as outlined by Art. 89(8) of the Medical Device Regulation or by Art. 84(8) of the In Vitro Diagnostic Medical Device Regulation;

o) by failing to adopt the necessary corrective actions contrary to Art. 90, subparagraph two of the Medical Device Regulation or contrary to Art. 85, subparagraph two of the In Vitro Diagnostic Medical Device Regulation;

p) by failing to update data in the electronic system in compliance with Art. 31(4) of the Medical Device Regulation or in compliance with Art. 28(4) of the In Vitro Diagnostic Medical Device Regulation; or

q) by failing to confirm the accuracy of submitted data in compliance with Art. 31(5) of the Medical Device Regulation or in compliance with Art. 28(5) of the In Vitro Diagnostic Medical Device Regulation.

(3) The manufacturer of a custom-made medical device commits an offence by

a) failing to draw up, keep up to date, and keep available for competent authorities documentation in compliance with Art. 10(5) of the Medical Device Regulation;

b) failing to report to the Institute information referred to under Section 8(4);

c) failing to submit to the Institute upon request thereof a list of medical devices made available by the manufacturer on the market within the territory of the Czech Republic in compliance with Section 8(5); or

d) contrary to Art. 21(2) of the Medical Device Regulation, failing to attach to a custom-made device a statement referred to under Annex XIII(1), which is available to the specific patient or user identified by name and surname, by an acronym or numeric code, or, contrary to Section 8(2) attaches this statement in a language other than the Czech.

(4) The authorised representative of a manufacturer commits an offence by

a) failing to provide to the Institute upon request thereof a copy of its authorisation compliant with Art. 11(2) and (3) of the Medical Device Regulation or compliant with Art. 11(2) and (3) of the In Vitro Diagnostic Medical Device Regulation;

b) failing to meet any of the obligations stipulated by Art. 11(3)(a) to (h) of the Medical Device Regulation or by Art. 11(3)(a) to (h) of the In Vitro Diagnostic Medical Device Regulation and specified in the authorisation in case the manufacturer is not established in a Member State;

c) failing to inform about the termination of its operation in compliance with Art. 11(6) of the Medical Device Regulation or in compliance with Art. 11(6) of the In Vitro Diagnostic Medical Device Regulation;

d) failing to have a person responsible for regulatory compliance pursuant to Art. 15(6) of the Medical Device Regulation or pursuant to Art. 15(6) of the In Vitro Diagnostic Medical Device Regulation;

e) failing to enter the data stipulated by Art. 31(1) of the Medical Device Regulation or by Art. 28(1) of the In Vitro Diagnostic Medical Device Regulation into the electronic system for the purposes of registration;

f) failing to update data in the electronic system in compliance with Art. 31(4) of the Medical Device Regulation or in compliance with Art. 28(4) of the In Vitro Diagnostic Medical Device Regulation; or

g) failing to confirm the accuracy of data submitted in compliance with Art. 31(5) of the Medical Device Regulation or in compliance with Art. 28(5) of the In Vitro Diagnostic Medical Device Regulation.

(5) For the commitment of an offence, a fine may be imposed up to the amount of

a) 200,000 CZK, where an offence referred to under paragraph (1)(a) or (w), paragraph (2)(e), (p) or (q), paragraph (3)(b), (c) or (d) or paragraph (4)(f) or (g) is concerned;

b) 500,000 CZK, where an offence referred to under paragraph (1)(g) or (z), paragraph (2)(k), paragraph (3)(a) or paragraph (4)(a), (c) or (e) is concerned;

c) 2,000,000 CZK, where an offence referred to under paragraph (1)(o) or (q) or paragraph (2)(i) or (j) is concerned;

d) 5,000,000 CZK, where an offence referred to under paragraph (1)(f), (i), (j), (m), (p), (s), (t), (u) or (v), paragraph (2)(b), (c), (f), (h) or (m) or paragraph (4)(d) is concerned;

e) 15,000,000 CZK, where an offence referred to under paragraph (1)(c), (k), (l), (x) or (y), paragraph (2)(d), (g), (l), (n) or (o) or paragraph (4)(b) is concerned; or

f) 30,000,000 CZK, where an offence referred to under paragraph (1)(b), (d), (e), (h), (n) or (r) or paragraph (2)(a) is concerned.

Section 56

Offences in the area of clinical investigations and performances studies of devices

(1) The sponsor of a clinical investigation or performance study commits an offence by

a) failing to conduct the clinical investigation or performance study in compliance with Art. 62(1), (3) or (4) of the Medical Device Regulation or in compliance with Article 57 or Art. 58(5) of the In Vitro Diagnostic Medical Device Regulation;

b) failing to ensure that the clinical investigation or performance study is conducted in compliance with Art. 72(1) of the Medical Device Regulation or in compliance with Art. 68(1) of the In Vitro Diagnostic Medical Device Regulation;

c) failing to ensure the monitoring of the clinical investigation or performance study in compliance with Art. 62(1) or Art. 72(2) of the Medical Device Regulation or in compliance with Article 57 or Art. 68(2) of the In Vitro Diagnostic Medical Device Regulation;

d) failing to safeguard the recording, processing or storage of any information about the clinical investigation or performance study in compliance with Art. 62(1) or Art. 72(3) of the Medical Device Regulation or in compliance with Art. 57(1) or Art. 68(3) of the In Vitro Diagnostic Medical Device Regulation;

e) failing to comply with the conditions for notification or conduct of clinical investigation or performance study stipulated by Article 74 of the Medical Device Regulation or by Article 70 of the In Vitro Diagnostic Medical Device Regulation;

f) making substantial changes to the plan of the clinical investigation or performance study without following the procedure stipulated by Article 75 of the Medical Device Regulation or by Article 71 of the In Vitro Diagnostic Medical Device Regulation;

g) failing to fulfil its information duty in case of suspension or termination of the clinical investigation or performance study in compliance with Art. 77(1) of the Medical Device Regulation or in compliance with Art. 73(1) of the In Vitro Diagnostic Medical Device Regulation;

h) failing to meet its notification duty at the time of ending the clinical investigation or performance study in compliance with Art. 77(3) of the Medical Device Regulation or in compliance with Art. 73(3) of the In Vitro Diagnostic Medical Device Regulation;

i) failing to submit the clinical investigation report or performance study report or summary in

compliance with Art. 77(5) of the Medical Device Regulation or in compliance with Art. 73(5) of the In Vitro Diagnostic Medical Device Regulation;

j) failing to report, by means of the electronic system, to the competent authorities of the Member State where the clinical investigation or performance study is being conducted, information referred to under Art. 80(2), (3) or (4) of the Medical Device Regulation or under Art. 76(2), (3) or (4) of the In Vitro Diagnostic Medical Device Regulation;

k) failing to ensure that, in compliance with Art. 62(2), subparagraph one (m) of the Medical Device Regulation or in compliance with Art. 58(4) of the In Vitro Diagnostic Medical Device Regulation, a natural or legal person established in a Member State of the European Union be appointed as its authorised representative, if the sponsor is not established in any Member State of the European Union;

l) failing to ensure, contrary to Art. 62(6) of the Medical Device Regulation or contrary to Art. 58(7) of the In Vitro Diagnostic Medical Device Regulation, that the investigator or other staff involved in the conduct of the clinical investigation or performance study meet the requirements stipulated by Art. 62(6) of the Medical Device Regulation or by Art. 58(7) of the In Vitro Diagnostic Medical Device Regulation; or

m) failing to establish a procedure for emergency situations in compliance with Art. 72(6) of the Medical Device Regulation or in compliance with Art. 68(6) of the In Vitro Diagnostic Medical Device Regulation.

(2) The investigator commits an offence by

a) failing to ensure that the clinical investigation or performance study is conducted in compliance with Art. 72(1) of the Medical Device Regulation or in compliance with Art. 68(1) of the In Vitro Diagnostic Medical Device Regulation; or

b) failing to safeguard the recording, processing, and storage of any information about the clinical investigation or performance study in compliance with Art. 72(3) of the Medical Device Regulation or in compliance with Art. 68(3) of the In Vitro Diagnostic Medical Device Regulation.

(3) For the commitment of an offence, a fine may be imposed up to the amount of

a) 200,000 CZK, where an offence referred to under paragraph (1)(h) is concerned;

b) 500,000 CZK, where an offence referred to under paragraph (1)(e), (g) or (k) or under paragraph (2)(b) is concerned;

c) 2,000,000 CZK, where an offence referred to under paragraph (1)(i) or (j) or under paragraph (2)(a) is concerned;

d) 5,000,000 CZK, where an offence referred to under paragraph (1)(c) or (d) is concerned;

e) 15,000,000 CZK, where an offence referred to under paragraph (1)(b), (f), (l) or (m) is concerned; or

f) 30,000,000 CZK, where an offence referred to under paragraph (1)(a) is concerned.

Section 57

Offences in the sphere of import of devices

(1) The importer commits an offence by

a) failing to ensure, for the purposes of placing the device on the market, that the device has met all of the requirements stipulated by Art. 13(2) of the Medical Device Regulation or by Art. 13(2) of the In Vitro Diagnostic Medical Device Regulation;

b) failing to meet the information duty stipulated by Art. 13(2) of the Medical Device Regulation or by Art. 13(2) of the In Vitro Diagnostic Medical Device Regulation;

c) placing a device on the market contrary to Art. 13(2) of the Medical Device Regulation or contrary to Art. 13(2) of the In Vitro Diagnostic Medical Device Regulation, although it believes or has a reason to believe that the device is not compliant with the requirements of the Medical Device Regulation or of the In Vitro Diagnostic Medical Device Regulation;

d) failing to provide information on the device, its labelling or in a document attached to the device as required by Art. 13(3) of the Medical Device Regulation or by Art. 13(3) of the In Vitro Diagnostic Medical Device Regulation;

e) failing to check whether the device has been registered in the electronic system or failing to add its data into the said registration in compliance with Art. 13(4) of the Medical Device Regulation or in compliance with Art. 13(4) of the In Vitro Diagnostic Medical Device Regulation;

f) failing to ensure storage or transport conditions in compliance with Art. 13(5) of the Medical Device Regulation or in compliance with Art. 13(5) of the In Vitro Diagnostic Medical Device Regulation or failing to observe the minimum requirements for the device safety in compliance with Section 27(2);

g) failing to keep the register of complaints, non-conforming devices and cases of device withdrawal or recall or by failing to provide the manufacturer, authorised representative, and distributors with data allowing to assess the complaint in compliance with Art. 13(6) of the Medical Device Regulation or in compliance with Art. 13(6) of the In Vitro Diagnostic Medical Device Regulation;

h) failing to meet the information duty or to cooperate with the manufacturer, authorised representative or Institute in compliance with Art. 13(7) of the Medical Device Regulation or in compliance with Art. 13(7) of the In Vitro Diagnostic Medical Device Regulation;

i) failing to forward a complaint or a suspected incident report to the manufacturer or authorised representative in compliance with Art. 13(8) of the Medical Device Regulation or in compliance with Art. 13(8) of the In Vitro Diagnostic Medical Device Regulation;

j) failing to keep EU declarations of conformity or, where applicable, copies of the relevant certificates of conformity, including any changes and amendments, in compliance with Art. 13(9) of the Medical Device Regulation or in compliance with Art. 13(9) of the In Vitro Diagnostic Medical Device Regulation;

k) failing to cooperate with the Institute in compliance with Art. 13(10) of the Medical Device Regulation or in compliance with Art. 13(10) of the In Vitro Diagnostic Medical Device Regulation;

l) failing to provide information or failing to ensure that a quality management system is in place in compliance with Art. 16(3) of the Medical Device Regulation or in compliance with Art. 16(3) of the In Vitro Diagnostic Medical Device Regulation;

m) failing to meet the information duty, failing to provide a sample or mock-up of the device or failing to submit the certificate in compliance with Art. 16(4) of the Medical Device Regulation or in compliance with Art. 16(4) of the In Vitro Diagnostic Medical Device Regulation;

n) failing to cooperate with manufacturers or authorised representatives in compliance with Art. 25(1) of the Medical Device Regulation or in compliance with Art. 22(1) of the In Vitro Diagnostic Medical Device Regulation;

o) being unable to identify the operator referred to under Art. 25(2) of the Medical Device Regulation or under Art. 22(2) of the In Vitro Diagnostic Medical Device Regulation;

p) failing to store or keep unique device identification in compliance with Art. 27(8) of the Medical Device Regulation or in compliance with Art. 24(8) of the In Vitro Diagnostic Medical Device Regulation;

q) failing to verify the entry of data or failing to add its data in compliance with Art. 30(3) of the Medical Device Regulation or in compliance with Art. 27(3) of the In Vitro Diagnostic Medical Device Regulation;

r) failing to enter data in compliance with Art. 31(1) of the Medical Device Regulation or in compliance with Art. 28(1) of the In Vitro Diagnostic Medical Device Regulation into the electronic system for the purposes of registration;

s) failing to update data in the electronic system in compliance with Art. 31(4) of the Medical Device Regulation or in compliance with Art. 28(4) of the In Vitro Diagnostic Medical Device Regulation; or

t) failing to confirm the accuracy of submitted data in compliance with Art. 31(5) of the Medical Device Regulation or in compliance with Art. 28(5) of the In Vitro Diagnostic Medical Device Regulation.

(2) For the commitment of an offence, a fine may be imposed up to the amount of

a) 200,000 CZK, where an offence referred to under paragraph (1)(s) or (t) is concerned;

b) 500,000 CZK, where an offence referred to under paragraph (1)(e), (j), (q) or (r) is concerned;

c) 2,000,000 CZK, where an offence referred to under paragraph (1)(a) or (l) is concerned;

d) 5,000,000 CZK, where an offence referred to under paragraph (1)(d), (f), (g), (k) or (m) is concerned;

e) 15,000,000 CZK, where an offence referred to under paragraph (1)(b), (h), (i), (n), (o) or (p) is concerned; or

f) 30,000,000 CZK, where an offence referred to under paragraph (1)(c) is concerned.

Section 58

Offences in the sphere of device distribution

(1) The distributor commits an offence by

a) failing to meet the notification duty set forth by Section 23 or by Section 25(1);

b) making a device available without instructions for use in the Czech language contrary to Section 26(2);

c) failing to observe the minimum requirements for device safety stipulated by Section 27(2);

d) making a device available on the market contrary to Art. 14(2) of the Medical Device Regulation or contrary to Art. 14(2) of the In Vitro Diagnostic Medical Device Regulation, although it believes or has a reason to believe that the device is not compliant with the requirements set forth by the Medical Device Regulation or by the In Vitro Diagnostic Medical Device Regulation;

e) failing to verify, contrary to Art. 14(2) of the Medical Device Regulation or contrary to Art. 14(2) of the In Vitro Diagnostic Medical Device Regulation, compliance with the requirements stipulated by this article prior to making the device available on the market;

f) failing to meet the information duty or failing to cooperate with the manufacturer, authorised representative or Institute in compliance with Art. 14(2) or (4) of the Medical Device Regulation or in compliance with Art. 14(2) or (4) of the In Vitro Diagnostic Medical Device Regulation;

g) failing to provide for storage or transport conditions in compliance with Art. 14(3) of the Medical Device Regulation or in compliance with Art. 14(3) of the In Vitro Diagnostic Medical Device Regulation;

h) failing to keep the register of complaints, non-conforming devices and cases of device withdrawal or recall or by failing to fulfil the information duty stipulated by Art. 14(5) of the Medical Device Regulation or by Art. 14(5) of the In Vitro Diagnostic Medical Device Regulation;

i) failing to submit information or documentation to the Institute upon request thereof, failing to submit samples to the Institute or failing to cooperate with the Institute in compliance with Art. 14(6) of the Medical Device Regulation or in compliance with Art. 14(6) of the In Vitro Diagnostic Medical Device Regulation;

j) failing to provide information or failing to ensure that it has a quality management system in place in compliance with Art. 16(3) of the Medical Device Regulation or in compliance with Art. 16(3) of the In Vitro Diagnostic Medical Device Regulation;

k) failing to meet the information duty, failing to provide a sample or mock-up of the device or failing to submit the certificate in compliance with Art. 16(4) of the Medical Device Regulation or in compliance with Art. 16(4) of the In Vitro Diagnostic Medical Device Regulation;

l) failing to cooperate with manufacturers or authorised representatives in compliance with Art. 25(1) of the Medical Device Regulation or in compliance with Art. 22(1) of the In Vitro Diagnostic Medical Device Regulation;

m) being unable to identify for the Institute the operator referred to under Art. 25(2) of the Medical Device Regulation or under Art. 22(2) of the In Vitro Diagnostic Medical Device Regulation; or

n) failing to store or keep unique device identification in compliance with Art. 27(8) of the Medical Device Regulation or in compliance with Art. 24(8) of the In Vitro Diagnostic Medical Device Regulation.

(2) For the commitment of an offence, a fine may be imposed up to the amount of

a) 500,000 CZK, where an offence referred to under paragraph (1)(a) is concerned;

b) 2,000,000 CZK, where an offence referred to under paragraph (1)(b), (e) or (j) is concerned;

c) 5,000,000 CZK, where an offence referred to under paragraph (1)(c), (g), (h), (i), (k) or (l) is concerned;

d) 15,000,000 CZK, where an offence referred to under paragraph (1)(f), (m) or (n) is concerned; or

e) 30,000,000 CZK, where an offence referred to under paragraph (1)(d) is concerned.

Section 59

Offences in the sphere of healthcare provider operation

(1) The provider of healthcare services commits an offence by

a) failing to report to the Institute the establishment or dissolution of an ethics committee in compliance with Section 13(1);

b) failing to keep records about the operation of an ethics committee established thereby for the stipulated period contrary to Section 13(3);

c) failing to ensure, contrary to Section 39(1)(a), that the device is used in compliance with the instructions of the manufacturer;

d) failing to ensure that a device with measuring function is operated in compliance with Section 39(1)(b);

e) failing to arrange for instruction of the person providing healthcare services in compliance with

Section 39(1)(c);

f) failing to ensure compliance with good storage practice pursuant to Section 39(1)(d);

g) failing to arrange for device servicing as required by Section 39(1)(e);

h) failing to make sure that the patient is given the manufacturer's statement for a custom-made device in compliance with Section 39(1)(f);

i) using a device contrary to Section 39(2);

j) failing to make a record in the healthcare documentation in compliance with Section 39(3);

k) failing to keep the unique identification of devices supplied thereto or failing to submit information to the Institute as required by Section 39(4);

l) failing to keep documentation about used devices in compliance with Section 39(5) or in compliance with the implementing regulation issued on the basis of Section 39(6);

m) failing to ensure that the person providing healthcare services has access to information in compliance with Section 40(1);

n) failing to provide the patient with information about the implanted implantable device in compliance with Section 40(2);

o) failing to ensure that the device is operated or used only by persons meeting the conditions stipulated by Section 41(1);

p) failing to keep the information about all completed trainings in compliance with Section 41(3);

q) failing to keep a record of safety technical control in compliance with Section 45(5) or failing to keep a record on repair in compliance with Section 46(3);

r) failing, as the manufacturer of devices referred to under Art. 5(5)(d) of the Medical Device Regulation or under Art. 5(5)(d) of the In Vitro Diagnostic Medical Device Regulation, to submit to the Institute upon request thereof information in compliance with Art. 5(5)(d) of the Medical Device Regulation or in compliance with Art. 5(5)(d) of the In Vitro Diagnostic Medical Device Regulation;

s) failing, as the manufacturer of devices referred to under Art. 5(5) of the Medical Device Regulation or under Art. 5(5) of the In Vitro Diagnostic Medical Device Regulation, to draw up or publish upon request the declaration referred to under Art. 5(5)(e) of the Medical Device Regulation or under Art. 5(5)(e) of the In Vitro Diagnostic Medical Device Regulation;

t) contrary to Section 50(1)(a), failing to implement the necessary measures in order to minimise negative consequences of an incident that has occurred;

u) contrary to Section 50(1)(b), failing to provide access to the device, including the complete documentation, for the manufacturer or for the Institute;

v) contrary to Section 50(1)(c), failing to provide in full the necessary cooperation and information for the purposes of establishing the cause of an incident that has occurred; or

w) contrary to Section 50(2), failing to keep information on a suspected serious incident in the medical documentation kept for the patient.

(2) For the commitment of an offence, a fine may be imposed up to the amount of

a) 200,000 CZK, where an offence referred to under paragraph (1)(a), (b), (h) or (v) is concerned;

b) 500,000 CZK, where an offence referred to under paragraph (1)(d), (e), (j), (m), (p), (q) or (w) is

concerned;

c) 2,000,000 CZK, where an offence referred to under paragraph (1)(g), (l), (n), (o), (r) or (s) is concerned; or

d) 5,000,000 CZK, where an offence referred to under paragraph (1)(c), (f), (i), (k), (t) or (u) is concerned.

Section 60

Offences in the sphere of device dispensing

(1) The dispensing person commits an offence by

a) dispensing a device contrary to Section 32;

b) breaching the prohibition stipulated by Section 33(2);

c) failing to meet any of the obligations set forth by Section 34 during mail-order dispensing of a device;

d) contrary to Section 35(1), replacing a device for another one that may not be replaced for the prescribed one during dispensing of a device prescribed on paper or electronic order;

e) contrary to Section 35(1), during dispensing of a device prescribed on paper order, failing to note the replacement made on the order;

f) contrary to Section 35(2), replacing device during dispensing thereof, although the order says “Replacement not allowed”;

g) failing to observe good storage practice as required by Section 37(a);

h) failing to provide the patient with the complete information in compliance with Section 37(b);

i) failing to store orders for dispensed devices in compliance with Section 37(c); or

j) failing to take out or store separately devices in compliance with Section 37(d).

(2) For the commitment of an offence, a fine may be imposed up to the amount of

a) 200,000 CZK, where an offence referred to under paragraph (1)(e) is concerned;

b) 500,000 CZK, where an offence referred to under paragraph (1)(c), (f), (h) or (i) is concerned; or

c) 2,000,000 CZK, where an offence referred to under paragraph (1)(a), (b), (d), (g) or (j) is concerned.

Section 61

Offences in the sphere of device prescribing

(1) A legal person or natural person-entrepreneur commits an offence by placing symbols or elements restricting the readability of the completed data, data about other providers of healthcare services or about dispensing persons or advertising statements on the paper order contrary to Section 28(6).

(2) A legal person or natural person-entrepreneur commits an offence by providing the electronic order identifier accompanied by a statement of advertising nature contrary to Section 29(5).

(3) The healthcare provider commits an offence by failing to ensure that the patient is provided with the identifier of the electronic order in compliance with Section 29(4).

(4) The prescriber commits an offence by providing the patient with the identifier of the electronic order for consideration contrary to Section 29(4).

(5) Offences referred to under paragraphs (1) to (4) may be fined in an amount up to 200,000 CZK.

Section 62

Offences in the sphere of device servicing

(1) The servicing person commits an offence by

a) failing to meet the notification duty set forth by Section 23 or by Section 25(1) or failing to confirm the accuracy of the data notified in this manner within the timeline of one year pursuant to Section 25(2);

b) failing to ensure that all staff conducting safety technical controls complete an up-to-date training in compliance with Section 45(4)(a);

c) failing to ensure that the safety technical control of an active risk class IIa medical device, of a risk class IIb or III medical device or of an in vitro diagnostic medical device is performed in compliance with Section 45(4)(b);

d) failing to ensure that the staff conducting safety technical control of a device which is an electrical apparatus meet the requirements stipulated by Section 45(4)(c);

e) failing to arrange for adequate material and technical equipment for the conduct of safety technical controls in compliance with Section 45(4)(d);

f) failing to ensure that a record on the conduct of a safety technical control is made in compliance with Section 45(5);

g) failing to ensure that all the staff conducting repairs complete an up-to-date training in compliance with Section 46(2)(a);

h) failing to ensure that the repair of an active risk class IIa medical device, of a risk class IIb or III medical device or of an in vitro diagnostic medical device is conducted in compliance with Section 46(2)(b);

i) failing to ensure that the staff conducting a repair of a device which is an electrical apparatus meet the requirements stipulated by Section 46(2)(c);

j) failing to arrange for adequate material and technical equipment for the conduct of repairs in compliance with Section 46(2)(f);

k) failing to ensure that following the completion of a repair, the safety and performance of the device is retested in compliance with Section 46(3); or

l) failing to ensure that a record of the conducted repair and retesting is made in compliance with Section 46(3).

(2) For the commitment of an offence, a fine may be imposed up to the amount of

a) 500,000 CZK, where an offence referred to under paragraph (1)(a) is concerned; or

b) 2,000,000 CZK, where an offence referred to under paragraph (1)(b), (c), (d), (e), (f), (g), (h), (i), (j), (k) or (l) is concerned.

Section 63

Common provisions on offences

(1) In the first instance, offences shall be considered by the Institute.

(2) Fines shall be collected by the Institute.

PART ELEVEN

COMMON, TRANSITIONAL, AND CLOSING PROVISIONS

Section 64

Granting of exemptions

(1) On the basis of a healthcare provider's request, the Ministry may decide on an authorisation to put into service a device in respect of which the conformity assessment procedures referred to under the Medical Device Regulation or under the In Vitro Diagnostic Medical Device Regulation have not been completed in case

a) of use of a device for a specific patient;

b) there is no adequate device available on the market for which the conformity assessment procedures have been completed; and

c) the use is in the interest of the safety or health of the patient referred to under latter (a).

(2) In compliance with the Medical Device Regulation or with the In Vitro Diagnostic Medical Device Regulation, the Institute may, upon request of the manufacturer, authorised representative or importer, authorise the placement on the market within the territory of the Czech Republic, the putting into service and use of a specific device in respect of which the conformity assessment procedures stipulated by the Medical Device Regulation or by the In Vitro Diagnostic Medical Device Regulation have not been completed if the use of the device is in the interest of public health protection or the safety or health of the patients.

(3) In addition to the particulars stipulated by the Code of Administrative Procedure, the request referred to under paragraph (1) or (2) must contain the reasons for granting the exemption, including supporting data therefor.

(4) In its decision, the competent authority shall stipulate the period for which the placement of the concerned device on the market or putting the device into service is authorised and the conditions under which the concerned device may be placed on the market or put into service or used.

Section 65

Ministry of Defence

(1) The Ministry of Defence, as a distributor, may divert from this Act if the purpose of such divergent procedure is to distribute a device for the provision of healthcare services

a) to soldiers on active duty within the territory of the Czech Republic during the state of war or state of emergency; or

b) to soldiers on active duty sent to fulfil the tasks of the armed forces of the Czech Republic or the Military Police outside the territory of the Czech Republic[18)].

(2) The Ministry of Defence, as a person servicing devices, may divert from this Act where the purpose of such divergent procedure is to service a device used by

a) a soldier on active duty within the territory of the Czech Republic during the state of war or

state of emergency; or

b) a solider on active duty sent to fulfil the tasks of the armed forces of the Czech Republic or the Military Police outside the territory of the Czech Republic[18)].

Reimbursement of costs of the conduct of expert tasks

Section 66

(1) The applicant shall be obliged to pay to the Institute reimbursement of costs of the conduct of expert tasks performed by the Institute.

(2) The applicant shall be obliged to reimburse the costs of expert tasks completed by the Institute in compliance with this Act, the Medical Device Regulation or the In Vitro Diagnostic Medical Device Regulation or those associated with

a) the drawing up of an expert opinion as referred to under Section 5(2)(m);

b) the provision of expert consultations referred to under Section 5(2)(m);

c) the assessment of a clinical investigation pursuant to Art. 62(1) or Art. 74(2) of the Medical Device Regulation or assessment of a performance study pursuant to Art. 58(1) and (2) or Art. 70(2) of the In Vitro Diagnostic Medical Device Regulation and assessment of modifications to the conditions of such clinical investigations or performance studies;

d) the assessment of another clinical investigation referred to under Article 82 of the Medical Device Regulation and modifications to the conditions of such clinical investigation;

e) the assessment of a clinical investigation referred to under Art. 74(1) of the Medical Device Regulation and modifications to the conditions of such clinical investigation; or

f) the assessment of a performance study referred to under Art. 70(1) of the In Vitro Diagnostic Medical Device Regulation and modifications to the conditions of such performance study.

(3) The specification of expert tasks, the method of determining the amount of reimbursement of costs of the conduct of expert tasks within the scope of individual activities, the maximum amount of reimbursement of the costs of the conduct of expert tasks within the scope of individual activities, and the amount of advance payments covering the reimbursement of costs of the conduct of expert tasks within the scope of individual activities are stipulated by the implementing legal regulation. The amount of reimbursement of costs of the conduct of expert tasks within the scope of individual activities shall be determined so as to cover the costs of the conduct of these expert tasks in the necessary amount.

(4) The Institute shall publish the typical times needed for the completion of expert tasks referred to under paragraph (2)(a) and (b) on its website.

Section 67

(1) The person on whose requests the expert tasks are to be performed shall be obliged to pay to the Institute an advance payment for the reimbursement of costs, if it is obvious that the expert tasks will be completed.

(2) The advance payment for the reimbursement of costs referred to under paragraph (1) shall be payable on the date of submission of the application. Where the applicant failed to pay the advance payment for the reimbursement of costs pursuant to paragraph (1) upon submission of the application, the Institute shall invite it to do so, stipulating the timeline for the payment; along with the invitation, the Institute may suspend the procedure. Where the applicant fails to pay the advance payment for the reimbursement of costs pursuant to paragraph (1) within the stipulated timeline, the Institute shall stop the procedure concerning the application.

(3) The Institute shall refund the reimbursement of costs to the applicant upon request of the latter

a) in full amount, if the applicant has paid reimbursement of costs without being obliged to do so;

b) in full amount, if the requested expert task has not been initiated; or

c) in an amount proportionate to the paid reimbursement of costs of expert tasks which have not been conducted.

(4) The applicant shall be obliged to pay up the difference between the advance payment for the reimbursement of costs referred to under paragraph (1) and the actual amount of reimbursement of costs in case the actual amount of reimbursement of costs exceeds the advance payment. The Institute shall charge the pay-up amount for the reimbursement of costs and shall determine the timeline for its payment.

(5) If the applicant fails to pay the pay-up amount for the reimbursement of costs pursuant to paragraph (4) within the stipulated timeline, the Institute shall invite it to do so and shall stipulate a timeline for the payment; along with the invitation, the Institute may suspend the procedure. Where the applicant fails to pay up the reimbursement of costs pursuant to paragraph (4) within the stipulated timeline, the Institute shall stop the procedure concerning the application.

(6) Matters of reimbursement of costs of the conduct of expert tasks shall be decided on by the Institute. The reimbursement of costs of the conduct of expert tasks shall be collected and enforced by the Institute.

(7) The reimbursement of costs pursuant to Section 66 shall not form an income of the state budget and shall be an income of a special account of the Institute which shall form part of the Institute's reserve fund. The Institute shall use these resources to safeguard its activities pursuant to this Act or pursuant to other legal regulations where such activities cannot be covered to the extent necessary from budgetary resources.

(8) If the government decides so, the Institute shall transfer the amount established by the government from the funds held on the account kept pursuant to paragraph (7) to the income account of the state budget of the Czech Republic opened for the Ministry.

Section 68

Powers of execution

The Ministry shall issue a decree implementing Section 22(3), (4), (5), and (7); Section 27(1); Section 28(3) and (7); Section 29(6); Section 31(7); Section 39(6); Section 51(2); and Section 66(3).

Transitional and closing provisions

Section 69

(1) The manufacturer of a custom-made medical device, the distributor or the person servicing devices who have notified their operation pursuant to existing legal regulations, shall be considered persons who have met their notification duty in compliance with Section 8 or 23 on the day of entry into force hereof. The day of entry into force hereof shall be considered the promulgation date.

(2) The data referred to under Section 23(2)(e)(1) and Section 23(2)(f)(1) shall be notified by the distributor or person servicing devices no later than within three months of the date of their publication in the Eudamed database. Until the date of notifying the data pursuant to Section 23(2)(e)(1), the distributor shall report the business name and the name of the generic group for the device[22)].

(3) A device that has been put into service prior to the date of entry into force hereof and has been properly CE-marked, or that has been properly market with the Czech conformity mark[23)], may be used in the provision of healthcare services in case it is being serviced in compliance with this Act.

(4) The sponsor shall notify another clinical investigation referred to under Article 82 of the Medical Device Regulation planned or initiated from 26 May 2021 until the launch of the Medical Device Information System via the Medical Device Information System as soon as this system is launched.

Section 70

(1) The person who has at least one year of practical experience in the sphere of conduct of safety technical controls of devices as of the date of entry into force hereof shall be considered the person complying with the requirement for expert qualification stipulated by Section 45(4)(b).

(2) The person who has at least one year of practical experience in the sphere of conduct of repairs of the concerned device or a similar type device as of the date of entry into force hereof shall be considered the person complying with the requirement for expert qualification stipulated by Section 46(2)(b).

Section 71

(1) Investigation into an incident of an in vitro diagnostic medical device reported to the Institute pursuant to Act No 268/2014 Coll. in the version effective prior to the date of entry into force hereof shall be completed in compliance with Act No 268/2014 Coll. in the version effective prior to the date of entry into force hereof.

(2) The monitoring of the conduct of safety corrective actions concerning in vitro diagnostic medical devices reported to the Institute pursuant to Act No 268/2014 Coll. in the version effective prior to the date of entry into force hereof shall be completed in compliance with Act No 268/2014 Coll. in the version effective prior to the date of entry into force hereof.

Section 72

(1) A performance study notified prior to the date of entry into force hereof pursuant to Act No 268/2014 Coll. in the version effective prior to the date of entry into force hereof, but not initiated prior to the date of entry into force hereof shall be considered not notified.

(2) The conduct of a performance study notified and initiated prior the date of entry into force hereof pursuant to Act No 268/2014 Coll. in the version effective prior to the date of entry into force hereof, shall proceed in compliance with existing legal regulations.

Section 73

(1) The Institute shall establish the Medical Device Information System no later than within twelve months of the date of entry into force hereof, or within six months of the date of launch of the Eudamed database, whichever occurs later.

(2) The Institute shall be obliged to ensure the provision of all data notified by the manufacturer of a custom-made medical device, distributor or person servicing devices pursuant to Act No 268/2014 Coll. in the version effective prior to the date of entry into force hereof, or pursuant to Act No 89/2021 Coll. in the version effective prior to the date of entry into force hereof, into the Medical Device Information System no later than within six months of the date of launching the Medical Device Information System.

(3) Until the launch of the Medical Device Information System, the Registry of Medical Devices established pursuant to Act No 268/2014 Coll. in the version effective prior to the date of entry into force hereof shall be used for the fulfilment of obligations stipulated by Sections 23 to 25.

(4) Until the launch of the Medical Device Information System, the Registry of Medical Devices established pursuant to Act No 268/2014 Coll. in the version effective prior to the date of entry into force hereof shall be used for the fulfilment of obligations stipulated by Section 22. The Institute shall be obliged to provide all of the data notified in this manner to the Medical Device Information System no later than within six months of the date of launching the Medical Device Information System.

(5) Until the launch of the Medical Device Information System, the Registry of Medical Devices established pursuant to Act No 268/2014 Coll. in the version effective prior to the date of entry into force hereof shall be used for the procedure stipulated by Section 10. Section 10(6) shall not be applicable prior to the launch of the Medial Device Information System.

Section 74

(1) Until the full functionality of the clinical investigations module in the Eudamed database, reporting of serious incidents arising in the course of clinical investigations of medical devices shall be done via the Registry of Medical Devices established by Act No 268/2014 Coll. in the version effective prior to the date of entry into force hereof.

(2) Until the full functionality of the performance studies module in the Eudamed database, reporting of serious incidents arising in the course of performance studies of in vitro diagnostic medical devices shall be done via the Registry of Medical Devices established by Act No 268/2014 Coll. in the version effective prior to the date of entry into force hereof.

(3) Until the full functionality of the clinical investigations module in the Eudamed database, applications for authorisation of clinical investigations pursuant to Article 62 and Art. 74(1) and (2) of the Medical Device Regulation shall be submitted via the Registry of Medical Devices established pursuant to Act No 268/2014 Coll. in the version effective prior to the date of entry into force hereof.

(4) Until the full functionality of the performance studies module in the Eudamed database, applications for authorisation of performance studies pursuant to Article 66 or notification thereof pursuant to Article 70 of the In Vitro Diagnostic Medical Device Regulation shall be submitted via the Registry of Medical Devices established pursuant to Act No 268/2014 Coll. in the version effective prior to the date of entry into force hereof.

(5) Until the full functionality of the clinical investigations module in the Eudamed database, the record-keeping of clinical investigations, submission of notifications of substantial modifications to clinical investigations, and the fulfilment of reporting duties of the sponsor pursuant to Article 77 of the Medical Device Regulation shall be done via the Registry of Medical Devices established by Act No 268/2014 Coll. in the version effective prior to the date of entry into force hereof.

(6) Until the full functionality of the performance studies module in the Eudamed database, the record-keeping of performance studies, submission of notifications of substantial modifications to performance studies, and the fulfilment of reporting duties of the sponsor pursuant to Article 73 of the In Vitro Diagnostic Medical Device Regulation shall be done via the Registry of Medical Devices established by Act No 268/2014 Coll. in the version effective prior to the date of entry into force hereof.

(7) Until the full functionality of the persons module in the Eudamed database, persons shall register via the Registry of Medical Devices established by Act No 268/2014 Coll. in the version effective prior to the date of entry into force hereof.

(8) Until the full functionality of the medical devices and in vitro diagnostic medical devices module in the Eudamed database, medical devices and in vitro diagnostic medical devices shall be notified via the Registry of Medical Devices established by Act No 268/2014 Coll. in the version effective prior to the date of entry into force hereof.

(9) Until the issuance of uniform structured forms for reporting of serious incidents or suspected serious incidents pursuant to Article 86 of the In Vitro Diagnostic Medical Device Regulation, reports shall be submitted to the extent stipulated by Act No 268/2014 Coll. in the version effective prior to the date of entry into force hereof.

(10) Where a medical device has been placed on the market prior to the full functionality of the Eudamed database in compliance with the conditions stipulated by Article 120 of the Medical Device Regulation and, at the same time, no device model identifier (basic UDI-DI) has been allocated thereto, a surrogate identifier allocated by the Eudamed database shall be used.

(11) Until the launch of the Medical Device Information System, the publication of field safety notices pursuant to Section 49(6) shall be done via the Registry of Medical Devices established by Act No 268/2014 Coll. in the version effective prior to the date of entry into force hereof.

Section 75

(1) A control initiated by the Institute prior to the entry into force hereof and still pending on the date of entry into force hereof shall be completed in compliance with existing legal regulations.

(2) Procedures concerning offences pursuant to Act No 268/2014 Coll. in the version effective prior to the date of entry into force hereof, or pursuant to Act No 89/2021 Coll. in the version effective prior to the date of entry into force hereof, initiated by the Institute prior to the date of entry into force hereof and still pending on the date of entry into force hereof shall be completed in compliance with existing legal regulations.

Section 76

Technical regulation

This Act has been announced in compliance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services.

Section 77

Repealing provisions

The following shall be repealed:

1. Part One of Act No 268/2014 Coll., on In Vitro Diagnostic Medical Devices.

2. Part Two Hundred and Thirty-Two of Act No 183/2017 Coll., Amending Some Acts in Association with the Adoption of the Act on Liability for Offences and Procedures Concerning Offences and Act on Some Offences.

3. Act No 366/2017 Coll., Amending Act No 268/2014 Coll., on Medical Devices and on Amendment to Act No 634/2004 Coll., on Administrative Fees, as amended by other regulations, as amended by Act No 183/2017 Coll.

4. Parts One to Eleven of Act No 89/2021 Coll., on Medical Devices and on Amendment to Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (Act on Pharmaceuticals), as amended.

5. Parts One and Four of Act No 90/2021 Coll., Amending Act No 268/2014 Coll., on Medical Devices and on Amendment to Act No 634/2004 Coll., on Administrative Fees, as amended, Act No 634/2004 Coll., on Administrative Fees, as amended, and Act No 40/1995 Coll., on Advertising Regulation and on Amendments to Act No 468/1991 Coll., on the Operation of Radio and Television Broadcasting, as amended, as amended.

6. Government Regulation No 56/2015 Coll., on technical requirements governing in vitro diagnostic medical devices.

7. Decree No 62/2015 Coll., implementing some provisions of the Act on In Vitro Diagnostic Medical Devices.

8. Decree No 170/2021 Coll., stipulating the amounts of reimbursement of costs of expert tasks performed by the State Institute for Drug Control pursuant to the Act on Medical Devices.

9. Decree No 171/2021 Coll., stipulating the amounts of reimbursement of costs of expert tasks performed by the State Institute for Drug Control pursuant to the Act on In Vitro Diagnostic Medical

Devices.

10. Decree No 186/2021 Coll., implementing some provisions of the Act on Medical Devices.

11. Decree No 187/2021, amending Decree No 62/2015 Coll., implementing some provisions of the Act on Medical Devices.

Section 78

Entry into force

This Act shall enter into force on day fifteen following its promulgation.

Pekarová Adamová, *manu propria*

Zeman, *manu propria*

Fiala, *manu propria*

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1) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, as amended.

2) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

3) Act No 22/1997 Coll., on Technical Requirements for Products and on Amendments to Some Acts, as amended.
Act No 90/2016 Coll., on Conformity Assessment of Specified Products When Made Available on the Market, as amended.

4) Act No 90/2016 Coll., as amended.

5) Section 101 of the Civil Code.

6) Art. 2(12) of the Medical Device Regulation or Art. 2(12) of the In Vitro Diagnostic Medical Device Regulation.

7) Article 30 of the Medical Device Regulation or Article 27 of the In Vitro Diagnostic Medical Device Regulation.

8) Section 66(3) of Act No 166/1999 Coll., on Veterinary Care and on Amendment to Some Related Acts (the Veterinary Act), as amended.

9) Part Seven of Act No 48/1997 Coll., on Public Health Insurance and on Amendments to Some Related Acts, as amended.

10) Section 19(4) of Act No 48/1997 Coll., as amended.

11) Section 32a(1) of Act No 48/1997 Coll., as amended.

12) Section 32(3)(b) and (c) of Act No 48/1997 Coll., as amended.

13) Annex 3 to Act No 48/1997 Coll., as amended.

14) Act No 40/1995 Coll., on Advertising Regulation and on Amendments to Act No 468/1991 Coll., on

the Operation or Radio and Television Broadcasting, as amended, as amended.

15) Chapter III(23.2)(i) of Annex I to the Medical Device Regulation or chapter III(20.2)(h) of Annex I to the In Vitro Diagnostic Medical Device Regulation.

16) Section 3 of Act No 505/1990 Coll., on Metrology, as amended.

17) Section 94(2) of Act No 221/1999 Coll., on Professional Soldiers, as amended.

18) Article 43 of Constitutional Act No 1/1993 Coll., the Constitution of the Czech Republic, as amended.
Section 3(1) of Act No 300/2013 Coll., on Military Police and on Amendment to Some Acts (Act on Military Police), as amended.

19) Standard ČSN EN 62353, standard ČSN EN 61010-2-101 ed. 2.

20) Annex 3 to Act No 111/1998 Coll., on Universities and on Amendments to Other Acts (Act on Universities), as amended.

21) Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products.

22) Art. 2(7) of the Medical Device Regulation or Art. 2(8) of the In Vitro Diagnostic Medical Device Regulation.

23) Act No 22/1997 Coll., as amended.