89/2021

ACT

of 9 February 2021

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

The Parliament adopted the following act of the Czech Republic:

PART ONE

INTRODUCTORY PROVISIONS

Section 1

Subject matter

(1) Following the directly applicable Regulation (EU) 2017/745 of the European Parliament and of the Council[1)] (hereinafter referred to as the "Medical Device Regulation"), this Act

a) regulates the powers of administrative authorities in the exercise of state administration in the area of medical devices;

b) complements the rules set forth by directly applicable regulations of the European Union governing the area of medical devices;

c) sets the rules governing the Medical Device Information System;

d) sets the rules for medical device prescribing and dispensing, their use and the conditions of their servicing;

e) regulates the merits of offences constituting of a breach of obligations stipulated by directly applicable regulations of the European Union governing the area of medical devices and of the obligations set forth hereby, as well as the amounts of fines for committing such offences.

(2) This Act shall not be applicable to in vitro diagnostic medical devices.

Section 2

For the purposes hereof, a device shall mean a medical device, medical device accessory, and product listed under Annex XVI to the Medical Device Regulation.

PART TWO

EXERCISE OF GOVERNMENTAL AUTHORITY

Section 3

Government authorities

Government authority as referred to hereunder shall be exercised by the following authorities:

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

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

c) Office for Standards, Metrology and Testing.

Section 4

Ministry

In the area of medical devices, the Ministry shall, in particular:

a) cooperate with respective authorities of the Member States and represent the Czech Republic in workgroups and committees of the European Union;

b) appoint the representatives of the Czech Republic in the Medical Device Coordination Group as per Art. 103 of the Medical Device Regulation;

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

d) revoke measures of the Institute classified by the European Commission (hereinafter referred to as the "Commission") as unjustified as per Art. 96 of the Medical Device Regulation;

e)

cooperate in the area of medical devices with other government authorities and notified bodies.

Institute

Section 5

(1) The Institute shall perform activities conferred by directly applicable regulations of the European Union governing the area of medical devices onto the Member State or its concerned authority, unless stipulated otherwise hereby and unless a power in the area of notified bodies pursuant to Art. 35 to 58 of the Medical Device Regulation is concerned, the execution of which is, pursuant to another legal regulation[2)], as amended, the responsibility of the Office for Standards, Metrology and Testing.

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

a)

represent the Czech Republic, within the scope of its powers, in workgroups 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 concerned authorities of foreign countries and of the European Union;

c)

receive reports from distributors and servicing persons;

d)

administer and operate the Medical Device Information System;

e)

decide on

1.
restricted and suspended deliveries of a device onto the market;

2.
procedures referred to under Art. 95(1) and Art. 98(1) and (4) of the Medical Device Regulation;

3.
device withdrawals from the market;

4.
device recalls;

5.
restricted or terminated use of a device;

f)
decide whether a product is covered by the Medical Device Regulation;

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

h)
conduct surveillance over the market pursuant to the Medical Device Regulation, this Act and the act governing conformity assessment of specified products upon their supply onto the market[3)];

i)
control compliance with this Act and with directly applicable regulations of the European Union governing the area of medical devices;

j)
issue certificates of free sale;

k)
decide as a first-instance authority about offences the merits of which are stipulated hereby;

l)
carry out educational activities, particularly in the form of professional lectures;

m)
upon request, draw up expert opinions and positions and give expert consultations;

n)
adopt measures referred to under Art. 87(10) of the Medical Device Regulation;

o)
keep and publish an up-to-date list of ethics committees established by healthcare service providers and notified to the Institute in compliance with Section 17(1);

p)
submit requests referred to under Art. 4(1) of the Medical Device Regulation;

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

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

s)
publish a list of dispensing persons who are granted access to the ePrescription System for the purposes of dispensing of devices prescribed on order as per Section 28(1)(a).

(3) In the execution of powers referred to herein, the Institute shall make use of data from the basic registry of inhabitants, within the following scope:

a) name(s) and surname;

b) address of residence or mailing address, if applicable;

c) date, place, and district of birth; for data subjects born abroad: date, place, and country of birth.

(4) In the execution of powers referred to herein, the Institute shall make use of data from the basic registry of persons, within the following scope:

a) business name(s), unless a natural person-entrepreneur is incorporated under the Companies Registry;

b) name(s) and surname of a foreign person;

c) agenda identifier of a natural person for the agenda of a registry of persons;

d) identification number of the person;

e) date of incorporation or date of entry in a registry governed by other legal regulations;

f) date of dissolution or date of deletion from a registry governed by other legal regulations;

g) legal form;

h) data mailbox type and data mailbox identifier, if such data mailbox has been made accessible;

i) statutory body, name(s), surname and address of residence for natural persons or name and registered office for legal persons;

j) registered office address of an entity entered in a registry of persons or place of business of a natural person;

k)
date of the last change of data kept in the registry of persons.

(5) In the execution of powers referred to herein, the Institute shall make use of data about addresses from the basic registry of territorial identification, addresses, and real estate.

Section 6

(1) In case of doubts, the Institute shall decide whether a product is covered by the Medical Device Regulation, either upon request or ex officio.

(2) Where the Institute cannot issue a decision on the basis of available source materials in a procedure referred to under paragraph (1), it shall file a request as per Art. 4(1) of the Medical Device Regulation and shall stop the procedure referred to under paragraph (1).

(3) The Institute shall issue a general measure restricting the manufacture or use of a specific device type as per Art. 5(5) of the Medical Device Regulation if it finds out that the use of the device poses a risk for patients, users or other persons or a public health risk.

(4) In the issuance of a general measure referred to under paragraph (3), the proposed measure shall be delivered and the general measure published by means of a public decree on the Institute´s notice board.

(5) A general measure referred to under paragraph (3) shall take effect on the fifteenth day after its publication on the Institute´s official notice board. The Institute may stipulate an earlier effective date, which, however, may not precede the date of publication on the notice board.

Section 7

Medical Device Information System

(1) The Institute shall be the administrator and operator of the Medical Device Information System, which is not publicly accessible, unless stipulated otherwise by law. The Medical Device Information System is a public administration information system intended primarily for data collection and administration and for the submission of notifications and applications to the Institute and, in cases specified by law, also for the provision of information to the public. Where the Medical Device Information System does not serve for the purposes of provision of information to the public, advanced authentication is required for access. The Medical Device Information System shall contain, in particular, data that have been obtained:

a)
from electronic systems as per the Medical Device Regulation;

b)
by the Institute pursuant to Section 8, 10, 17, and 23 and pursuant to Art. 16(4) and Art. 82 of the Medical Device Regulation.

(2) The information referred to under Art. 33 of the Medical Device Regulation, data about persons who notified their operation as per Section 23, and data about concerned devices shall be published via the Medical Device Information System in a manner allowing for remote access.

(3) Upon request of the manufacturer or their authorised representative, the Institute shall remove the association between the manufacturer or their authorised representative and the servicing person from the Medical Device Information System.

(4) Information referred to under Art. 16(4) of the Medical Device Regulation shall be submitted by distributors or importers to the Institute via the Medical Device Information System.

PART THREE

MANUFACTURER´S OBLIGATIONS; SINGLE-USE DEVICE REPROCESSING; CERTIFICATE OF FREE SALE

Section 8

Manufacturer´s obligations

(1) A manufacturer or their authorised representative who has their registered office within the territory of the Czech Republic or who places a device on the market within the territory of the Czech Republic or makes a device available on the market within the territory of the Czech Republic shall be obliged to provide the Institute, upon request of the latter, with any information and documentation necessary to evidence device conformity in the Czech, Slovak or English language. The manufacturer shall be obliged to ensure that the declaration of conformity referred to under Art. 19(1) of the Medical Device Regulation be translated into the Czech, Slovak or English language for devices that are made available on the market within the territory of the Czech Republic.

(2) The manufacturer shall be obliged to provide the information referred to under Art. 10(11) of the Medical Device Regulation and information listed under Art. 18(1)(a) to (d) of the Medical Device Regulation in the Czech language.

(3) Where the manufacturer fails to meet the obligation stipulated by sentence one of Art. 31(5) of the Medical Device Regulation, the Institute may, in compliance with sentence two of Art. 31(5) of the 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 shall be obliged to provide the Institute with the following information, and shall do so using the Medical Device Information System:

a) information about the start of operation within 30 days of the start of the manufacture of the custom-made device;

b)

a list of generic groups of the manufactured devices made available on the market within the territory of the Czech Republic within 6 months of the start of manufacture of the custom-made device;

c)

information about termination of operation.

(5) The manufacturer of a custom-made device shall be obliged to submit to the Institute, upon request of the latter, a list of devices made available by the former on the market within the territory of the Czech Republic, for a period of no more than 10 years, and in respect of implantable devices, for the period of no more than 15 years preceding the date of submission of the request by the Institute.

(6) The Institute shall assign each manufacturer of custom-made devices who notifies the start of their operation pursuant to paragraph (4) a registration number via the Medical Device Information System.

Section 9

Single-use device reprocessing

(1) Single-use device reprocessing is prohibited in the Czech Republic.

(2) The placing of reprocessed single-use devices on the market within the territory of the Czech Republic and making such devices available on the market within the territory of the Czech Republic and their use within the territory of the Czech Republic is prohibited.

Section 10

Issue of certificate of free sale

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

(2) In addition to the particulars stipulated by the Code of Administrative Procedure, the application must contain:

a)

the primary device model identifier (basic UDI-DI) in the UDI system pursuant to Art. 27 of the Medical Device Regulation, if allocated; and

b)

information whether the issue of the certificate of free sale is required in electronic or paper-based form.

(3) The Institute shall check in the European Database of Medicinal Products (hereinafter referred to as the "Eudamed") that the concerned device has been registered and

that no change preventing the issue of the certificate of free sale has occurred since the registration date.

(4) The Institute shall issue the certificate of free sale for the applicant via the Medical Device Information System, in the form of a certificate referred to under the Code of Administrative Procedure in the Czech and English language in compliance with Art. 60 of the Medical Device Regulation, or shall decline the request, doing so without unnecessary delay.

PART FOUR

CLINICAL EVALUATIONS AND CLINICAL INVESTIGATIONS

General provisions governing clinical evaluations and clinical investigations

Section 11

(1) The sponsor shall be liable to the clinical investigation subject for injuries suffered by the latter due to participation in a clinical investigation conducted within the territory of the Czech Republic. For these cases, the sponsor shall be obliged to contract insurance covering the sponsor´s liability for compensation of damage arising from the conduct of the clinical investigation, whereas such insurance must be concluded for the duration of the clinical investigation and cover the full liability of the sponsor. The insurance coverage must be adequate to the risks associated with the conducted clinical investigation.

(2) The contracted insurance referred to under paragraph (1) may be terminated on the part of the insurer no later than as of the day preceding the date on which the clinical investigation is to commence. In case the clinical investigation is ongoing and the insurer finds out that a reason has occurred which would otherwise result in contract termination, it shall be entitled to require the sponsor to compensate the paid insurance claims up to the agreed insurance amount, paid by the insurer on the basis of the contract; in such a case, the insurer may terminate the contract only as of the clinical investigation end date. This shall be without prejudice to the sponsor´s liability to compensate injuries to clinical investigation subjects.

(3) If the insurer has terminated the contract pursuant to paragraph (2), it shall forthwith inform the Institute to this effect, including identification of the terminated contract, parties thereto and the reason for which the contract has been terminated thereby.

Section 12

(1) The sponsor shall be obliged to ensure that the clinical investigation documentation stipulated by the Medical Device Regulation be kept for the period of time set forth by Annex XV to the Medical Device Regulation even in case of the sponsor´s bankruptcy or termination of operation.

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

(3) In case new significant information that could have an impact upon the risk/benefit profile of the investigated medical 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.

(4) Where practicable, the opinion of minors of incomplete legal capacity on their potential participation in the clinical investigation shall be sought. If appropriate with regard to the intellectual and volitional maturity of such persons, adequate to the person´s age, the informed consent may be granted also by such persons. The investigator shall, without unnecessary delay, inform the minor´s guardian or carer about the established opinion of or informed consent granted by the minor. The investigator shall record the established opinion of this person or the reason why such opinion could not be established in the medical documentation kept for the minor.

(5) The ethics committee opinion must form part of the dossier at the time of submission of the application for clinical investigation.

(6) A clinical investigation referred to under Art. 70(7)(a) of the Medical Device Regulation may not be commenced without a prior authorisation obtained from the Institute. The Institute shall notify the sponsor of the clinical investigation about the authorisation within timelines stipulated by Art. 70(7)(b) of the Medical Device Regulation.

(7) The timelines set forth in Art. 70(1) and (3) of the Medical Device Regulation shall be extended by 5 days.

Section 13

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

(2) The sponsor of another clinical investigation referred to by Art. 82 of the Medical Device Regulation shall contract insurance covering the sponsor´s liability for compensation of damage arising from the conduct of the clinical investigation as per Section 11(1) and shall submit the proof of insurance cover as referred to under Annex XV(II)(4.3) of the Medical Device Regulation.

(3) The sponsor of another clinical investigation referred to by Art. 82 of the Medical Device Regulation shall be obliged to submit a notification of their intention to conduct the clinical investigation to the Institute, and shall do so via the Medical Device Information System within 60 days prior to the commencement of the investigation. Such notification shall include documentation referred to under Annex XV(II)(1), (2), (3), (4.2), and (4.4) of the Medical Device Regulation. The clinical investigation may be commenced after the expiry of 60 days of the notification, unless the Institute decides otherwise. An implementing legal regulation shall stipulate the particulars of such notification; the notification shall include data identifying the clinical investigation, the sponsor of the clinical investigation, and the site where the clinical investigation is to be conducted, as well as the planned dates of commencement and termination of the clinical investigation.

(4) The sponsor of another clinical investigation referred to by Art. 82 of the Medical Device Regulation shall be obliged to notify the Institute of any serious adverse events referred to by Art. 2(58) of the Medical Device Regulation, and shall do so via the Medical Device Information System. An implementing legal regulation shall stipulate the particulars of such notification; the notification shall include 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 of the termination and conclusions of another clinical investigation referred to by Art. 82 of the Medical Device Regulation, and shall do so via the Medical Device Information System within 15 days of the termination of the investigation, and shall provide the conclusions thereof within 3 months of its termination.

(6) Art. 72(5) of the Medical Device Regulation shall be adequately applicable also to other clinical investigations referred to in Art. 82 of the Medical Device Regulation. In order to protect the life and health of clinical investigation subjects, the Institute may decide not to allow the commencement of a clinical investigation or, with a view to a finding, early terminate an ongoing clinical investigation ex officio.

(7) The sponsor of another clinical investigation referred to by Art. 82 of the Medical Device Regulation shall be obliged to notify the Institute via the Medical Device Information System of substantial modifications to the documentation of this clinical investigation defined under Art. 75(1) of the Medical Device Regulation and submit a written approval of such modifications issued by the ethics committee no later than 30 days prior to their implementation.

Section 14

Special provisions on clinical investigation subjects

(1) Unless stipulated otherwise below, a clinical investigation subject must not be a person in custody or security detention or confined, on the basis of a judicial order, to a facility with restricted personal liberty, or a person to whom healthcare services are provided without his/her consent.

(2) Where a clinical investigation has been started in a person who is taken into custody or security detention, such person must be forthwith withdrawn from the clinical investigation. This shall not apply where the termination of such person´s participation in the clinical investigation would jeopardize the person´s health. In such a case, the Prison Service of the Czech Republic shall enable the person to continue his/her participation in the clinical investigation for the necessary period of time, for the purposes of which it shall cooperate as necessary.

Ethics Committee

Section 15

(1) An ethics committee is an independent body of a healthcare service provider that

performs an ethics review of a clinical investigation in order to assess, with emphasis placed upon the ethical aspects, whether the rights, safety, dignity, and quality of life of clinical investigation subjects are protected and whether these aspects prevail over any other interests. The ethics committee acts via the healthcare service provider that established it. The ethics committee is not an administrative body and the Code of Administrative Procedure shall not apply to the issuance of opinions and procedures of the ethics committee.

(2) The ethics committee issues a favourable opinion on the conduct of a clinical investigation of a medical device in writing and exercises supervision over the conduct of the clinical investigation from the perspective of objectives set forth under paragraph (1). For this purpose, it shall evaluate, in particular, the professional competence of investigators, including the principal investigator, the adequacy of selected procedures and groups of clinical investigation subjects, and shall provide an opinion on the clinical investigation protocol and documents used to provide information to clinical investigation subjects and to obtain their informed consent, independently of the sponsor of the clinical investigation and the investigator.

(3) The ethics committee conducts supervision over the course of the clinical investigation for which it has issued a favourable opinion, at intervals adequate to the degree of risk for the clinical investigation subjects, no less, however, than on an annual basis, in compliance with paragraph (1) and with the procedures stipulated by Section 17(2). If, in case of dissolution of the ethics committee in the course of the clinical investigation, its operation is not taken over by another ethics committee no later than as of the date of dissolution of the former, the ethics committee´s favourable opinion on the conduct of the clinical investigation shall become void.

Section 16

(1) The ethics committee shall be established by the healthcare service provider. The ethics committee may also operate as the ethics committee of another healthcare service provider, on the basis of a written contract concluded by the healthcare service providers. In such a case, the conditions for ethics committee operation shall be safeguarded by the healthcare service provider that is the founder of the ethics committee.

(2) The healthcare service provider shall appoint members of the ethics committee in writing. The ethics committee shall have at least 5 members. At least one of the ethics committee members must be a person without healthcare education and without professional scientific qualification in the sphere of healthcare and at least one of the ethics committee members must be a person who is not in employment or other similar labour relationship or another dependent position in respect to the healthcare service provider establishing the ethics committee or operating the healthcare facility where the proposed clinical investigation is to be conducted, and these two persons must be two different individuals. At least 4 members of the ethics committee must have the education of a medical doctor, dentist, pharmacist or a non-medical healthcare professional as per another legal regulation governing the competences for the execution of the healthcare profession of a medical doctor, dentist, pharmacist or a non-medical healthcare professional, and at least 3 members of the ethics committee must have the education of a medical doctor, dentist or a pharmacist and at least 5 years of practical experience in their field of specialisation. Prior to the appointment of the ethics committee members, the healthcare service provider establishing the ethics committee

shall request their written consent with membership in the ethics committee and observation of the obligations stipulated by paragraph (4). The members of the ethics committee shall elect one of them to act as the chairperson of the ethics committee. When appointing new members of the ethics committee after the ethics committee is established, an analogous procedure shall be followed. In order to obtain advice on a specific request for opinion, the ethics committee may invite other experts, whereas paragraph (4) shall be applicable to those invited members analogously.

(3) An ethics committee member may only a be a person of good repute, over 18 years of age, whose legal capacity has not been restricted. A person of good repute shall mean a natural person meeting the conditions of good repute stipulated by another legal regulation governing competence to perform the healthcare profession of a medical doctor, dentist, and pharmacist or a nonmedical healthcare professional. The natural person shall prove his/her good repute by means of an excerpt from the Criminal Record pursuant to another legal regulation governing the Criminal Record and, furthermore, by means of a document equivalent to the excerpt from the Criminal Record issued by the state of which the natural person is a citizen, as well as equivalent documents issued by states within the territories of which the natural person stayed for an uninterrupted period of more than 6 months over the past 3 years. The excerpt from the Criminal Record and the documents evidencing the good repute of the natural person must not be older than 3 months. The procedure of recognition of a document of good repute issued by the competent authority of another Member State of the European Union shall follow the Act on the Recognition of Professional Qualifications.

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

a) maintain confidentiality in respect of information and facts pertaining to the course of the clinical investigation, in particular the condition of health of clinical investigation subjects and the results of the clinical investigation disclosed thereto in association with his/her membership in the ethics committee;

b) forthwith report the existence of his/her personal interest in the assessed clinical investigation, or the origination of such interest;

c) refrain from providing his/her opinion on requests for approval of the conduct of a clinical investigation, in the conduct of which he/she has his/her personal interest, as well as from the exercise of professional supervision over such clinical investigations;

d) confirm in writing that he/she is aware of these aforementioned obligations.

Section 17

(1) The healthcare service provider shall notify the Institute via the Medical Device Information System of the establishment and dissolution of the ethics committee and changes in its membership, and shall do so within 30 days of the establishment or dissolution of the ethics committee or the change in its membership. Information on the dissolution of the ethics

committee shall be notified by the healthcare service provider also to all sponsors of clinical investigations the conduct of which is supervised by the concerned ethics committee. The notification shall include the name of the ethics committee, address, telephone number in a public telephone network, and electronic mail address, the members of the ethics committee, specifying the professional specialisation of the ethics committee members, the name and surname of the ethics committee chairperson, and the date of ethics committee establishment or dissolution.

(2) The ethics committee shall operate in accordance with written operating procedures. The procedures governing the assessment of requests for opinions on the clinical investigation and supervision over its conduct must be compatible with the procedures for the assessment of an application for clinical investigation authorisation set forth by the Medical Device Directive and must contain at least:

a) data about the ethics committee membership to the extent of the names and surnames of the members and their qualifications, and data about the healthcare facility for which it has been established by the healthcare service provider;

b) the methods and procedures for the assessment of requests for ethics committee opinion on a clinical investigation of a medical device and the exercise of ongoing supervision over the clinical investigation, including the method of planning meetings and their notification to ethics committee members as well as the method of conducting such meetings;

c) procedures for expedited assessment and issuance of an opinion on administrative changes to an ongoing clinical investigation;

d) the methods of processing of reports from investigators and of information obtained from the clinical investigation supervision or via other routes;

e) the procedure for the issuance of an opinion on a clinical investigation and its notification to the investigator or healthcare service provider, procedures for the review of opinions and revocation of opinions;

f) procedures for the fulfilment of information obligations stipulated by law.

(3) The healthcare service provider shall be obliged to keep all records of operation of the ethics committee established thereby for the period of least 3 years after the termination of the clinical investigation.

(4) In case of ethics committee dissolution, the healthcare service provider who established the ethics committee shall inform the Institute whether the activities of the dissolved ethics committee are to be taken over by another ethics committee, and shall provide a list of ongoing clinical investigations supervised by the dissolved ethics committee,

and ways of ensuring the storage and hand-over of a copy of the documentation of the dissolved ethics committee to another ethics committee. In case supervision by another ethics committee has not been organised, the ongoing clinical investigation at the concerned healthcare service provider must be suspended until supervision over the clinical investigation is taken over by another ethics committee. The sponsor of the concerned clinical investigation shall ensure that new subject recruitment for the clinical investigation is suspended and that the follow-up of previously enrolled clinical investigation subjects continues in compliance with the clinical investigation plan.

(5) The Institute shall publish a list of ethics committees in the Czech Republic via the Medical Device Information System, specifying, in particular, the name of the ethics committee, the contact addresses of the ethics committee, the professional specialisation of its members, the date of establishment of the ethics committee, and, where applicable, the date of dissolution of the ethics committee.

Procedure to be followed in the issuance of ethics committee opinion

Section 18

(1) Where a clinical investigation, for which a favourable opinion has been issued by the ethics committee established by the healthcare service provider operating this healthcare facility, is conducted in the healthcare facility, the management of the healthcare facility shall create such conditions that ensure that this ethics committee may operate for the duration of the clinical investigation in this healthcare facility, and, if changes to the ethics committee membership occur, that flawless continuation of its operation as well as its rights and obligations be safeguarded.

(2) Upon the sponsor´s request, the ethics committee shall issue its opinion on the concerned clinical investigation. The sponsor shall be obliged to reimburse reasonably incurred costs arising in association with the issuance of such opinion of the ethics committee to the healthcare service provider whose body the ethics committee is.

(3) The ethics committee shall issue its opinion on the clinical investigation at its meeting, summoned in advance in compliance with the operating procedures referred to under Section 17(2). A quorum shall exist, if the ethics committee meeting is attended by the minimum of 5 members of the ethics committee of which one must be a person without healthcare education and without professional scientific qualification in the sphere of healthcare and at least 4 members must be educated as medical doctors, dentists, pharmacists or non-medical healthcare professionals pursuant to another legal regulation governing the competence to conduct the healthcare profession of a medical doctor, dentist, and pharmacist or a non-medical healthcare professional, whereas at least one of the ethics committee members with healthcare education must be a person who is not in employment or other similar labour relationship or another dependent position in respect to the healthcare service provider establishing the ethics committee or operating the healthcare facility where the proposed clinical investigation is to be conducted. The opinions of the ethics committee shall be taken by an absolute majority of votes of all attending members. Where the votes are tied, the chairperson´s vote shall prevail. The vote may be taken only by those ethics committee members who have been involved in the consideration of the specific request for opinion. The investigators of the concerned clinical investigations shall not participate in the adoption of

the ethics committee opinion.

(4) The ethics committee shall be obliged to minute its meetings. The minutes of ethics committee meetings shall contain the date, hour, and venue of the meeting, a list of attending ethics committee members, a list of other attending invited guests, major points on agenda, a record of the opinion, including a protocol on the resulting vote regarding the ethics committee opinion, a record of notification of potential conflict of interests of the ethics committee members, and a signature of at least one member of the ethics committee.

Section 19

(1) In the preparation of its opinion, the ethics committee shall assess whether the conditions stipulated by Art. 62(4)(d) to (k) of the Medical Device Regulation et seq. have been met, employing the ethics principles and methods referred to under Annex XV(I) of the Medical Device Regulation. In doing so, it shall assess:

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

b) whether the anticipated risk/benefit evaluation is acceptable and whether its conclusions are substantiated;

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

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

e) the Investigator´s brochure drawn up in compliance with Annex XV(II)(2) of the Medical Device Regulation;

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

g) where a clinical investigation involving incapacitated subjects is concerned, whether the manner of provision of the information referred to under Art. 63(2) of the Medical Device Regulation is adequate to the ability of such persons to understand the information;

h) whether adequate indemnification has been ensured for the subjects of the clinical investigation should harm be suffered thereby due to the clinical investigation; in

particular, all of the insurance policies concluded to cover the liability for damages pursuant to Section 11(1) shall be assessed;

i) the method of clinical investigation subject recruitment;

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

(2) In the assessment of compensations and insurance, the ethics committee shall always assess whether:

a) the indemnification for clinical investigation subjects in case of harm arising from their participation in the clinical investigation has been adequately covered by the insurance policy;

b) the liability of the investigator and of the sponsor to indemnify suffered harm has been adequately covered by the insurance policy or, if applicable, whether the investigator´s or sponsor´s liability insurance forms part of their labour relationship;

c) the compensation is not greater than the expenses incurred by the clinical investigation subject or the investigator in association with their involvement in the clinical investigation and whether the remuneration for investigators is known in advance and fixed and whether the investigator has submitted, together with the request, a written statement of the amount of such remuneration.

(3) In respect of clinical investigations where the subject´s informed consent cannot be obtained prior to the subject´s enrolment in the clinical investigation, the ethics committee shall assess the protocol procedure to request the informed consent from the clinical investigation subject´s legal guardian or carer or from the subject himself/herself, and shall consider whether it might be appropriate to condition the enrolment of any individual subjects by its approval.

Section 20

(1) The ethics committee shall issue its opinion on the clinical investigation on a basis of a written request and having assessed the submitted documentation. The request shall be submitted to the ethics committee by the investigator or 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.

(2) Along with its request for opinion on the clinical investigation, the applicant shall submit source materials necessary for the assessment of the clinical investigation by the ethics committee, in particular, documentation allowing the ethics committee to assess facts referred to under Section 19(1). In the course of assessment, the ethics committee shall be entitled to

request other documents and additional information from the sponsor as necessary for the assessment of the given facts. Where the ethics committee requests the documents or information referred to in sentence two, the timeline for the issuance of the ethics committee opinion as per paragraph (3) shall be suspended until the delivery of the documents or information to the ethics committee.

(3) Within 60 days of the delivery of the request, the ethics committee shall issue its written justified opinion on the concerned clinical investigation for the sponsor. The opinion of the ethics committee shall contain:

a) identification data of the assessed clinical investigation, in particular, the title of the clinical investigation, specification of the sponsor and the clinical investigation site, clinical investigation protocol number, or, if applicable, the clinical investigation identifier from Eudamed, the date of delivery of the application for clinical investigation authorisation, and a list of clinical investigation sites for which the ethics committee has provided its opinion and over which it carries out supervision;

b) a list of ethics committee members and their specialisation;

c) a list and identification of assessed documents;

d) a record of the resulting vote, a statement whether the ethics committee grants its approval of or declines the clinical investigation and a rationale of such statement;

e) the date of issue of the opinion and a signature of the member of the ethics committee authorised in this respect; and

f) in respect of clinical investigations where the subject´s informed consent cannot be obtained prior to the subject´s enrolment in the clinical investigation, the ethics committee shall explicitly state whether it approves of the subject enrolment procedure outlined in the protocol, and shall state whether it conditions the enrolment of any individual subject by its approval; where the enrolment of each individual subject is conditioned by the ethics committee approval, the ethics committee shall, moreover, specify the procedure to be employed by the investigator in requesting such approval and the procedure to be employed by the ethics committee in providing its opinion without any delay.

Section 21

The sponsor shall be obliged to notify the ethics committee who issued its opinion on the concerned clinical investigation, of any substantial modifications of the clinical investigation. Such notification must be made in writing and contain the reasons for the modification. Along with the notification, the sponsor shall submit a draft of revised relevant

part of the documentation affected by such modification and by the amendment to the protocol. Where a minor modification is concerned, the sponsor shall forthwith inform the Institute and the ethics committee who issued its opinion on the clinical investigation. In the assessment of a substantial modification of the clinical investigation and issuance of opinion on such modification, the ethics committee shall analogously follow the procedure outlined under Sections 18 to 20.

Section 22

(1) Where the ethics committee learns of new facts relevant for the safety of the clinical investigation subjects or where the sponsor or investigator seriously breaches the conditions of the conduct or design of the clinical investigation for which the ethics committee issued its favourable opinion, the ethics committee shall revoke or suspend its favourable opinion. The revocation/suspension of the favourable opinion shall contain the clinical investigation identification data, a rationale, measures to be taken to terminate the clinical investigation, date of the revocation/suspension of the approval, and a signature of the ethics committee member authorised in this respect. Except for cases where the safety of the clinical investigation subjects is jeopardised, the ethics committee, prior to revoking/suspending its favourable opinion, shall request the position of the sponsor or, if applicable, of the investigator.

(2) The revocation/suspension of its favourable opinion as per paragraph (1) shall be notified forthwith by the ethics committee to the investigator, sponsor, and the Institute. The revocation/suspension of the ethics committee approval shall contain:

a) identification data of the clinical investigation, in particular, the title of the clinical investigation, specification of the sponsor and the clinical investigation sites for which the approval is being revoked/suspended, clinical investigation protocol number, or, if applicable, the clinical investigation identifier in the Eudamed database;

b) a rationale for the revocation/suspension of the approval;

c) measures to be taken to terminate the clinical investigation, in particular, the options to switch patients to another therapy, where the approval has been revoked/suspended due to jeopardised safety of the clinical investigation subjects and unless these have already been specified in the clinical investigation protocol;

d) the date of the revocation/suspension of the approval and a signature of the ethics committee member authorised in this respect.

PART FIVE

OBLIGATIONS OF DISTRIBUTORS AND SERVICING PERSONS

Section 23

(1) Distributors and servicing persons shall be obliged to notify the Institute, via the Medical Device Information System, of their operation of a device distributor or servicing person and shall do so prior to the commencement of their operation. This obligation shall not apply to persons servicing solely risk class I devices, and to distributors supplying solely risk class I devices or those supplying a device solely to the user who is not a healthcare service provider.

(2) In addition to the particulars prescribed by the Code of Administrative Procedure, the notification referred to under paragraph (1) must contain the following:

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

b)
definition of the notified operation;

c)
for the person of a distributor in relation to devices intended to be supplied thereby onto the market within the territory of the Czech Republic, except for risk class I devices:

1.
the primary identifier of the device model (basic UDI-DI) in the UDI system as per Art. 27 of the Medical Device Regulation; and

2.
the intended purpose of the device[4)] defined in the instructions for use;

d)
for persons servicing devices:

1.
a list of single registration numbers of manufacturers[5)] of those devices the person intends to service; and

2.
a copy of a document evidencing training in compliance with Section 45(4)(a) or Section 46(2)(a) from each manufacturer or a person authorised by the latter, or, if applicable, from the authorised representative of the concerned manufacturer or a person authorised thereby, and a copy of the authorisation of such person by the manufacturer or authorised representative; such documents shall not be required where the servicing is conducted directly by the manufacturer of the device in question.

Section 24

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

(2) The Institute shall delete data notified pursuant to Section 23 from the Medical Device Information System, if such deletion is requested by the person who filed the notification, and shall inform the person of such act by means of a notice.

(3) Where the Institute ex officio finds out that the data notified pursuant to Section 23 do not reflect reality, it shall invite the person who notified the data to remedy the situation within a timeline stipulated by the Institute. If the timeline expires without result, the Institute shall decide on the deletion of the data notified as per Section 23 from the Medical Device Information System.

Section 25

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

(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 as referred to in this sentence, the notified person shall be obliged to confirm the accuracy of the notified data. Thirty days prior to the expiry of the timeline referred to under sentence one, the Institute shall send a reminder of the necessity to confirm the accuracy of the notified data to the notified person via the Medical Device Information System.

(3) Where the data accuracy is not confirmed within the timeline referred to under paragraph (2) sentence one, the data pertaining to the notified person in the Medical Device Information System shall become invalid and shall be made non-public in the Medical Device Information System. The Institute shall inform the notified person to this effect by means of a notice. On the basis of a request of the concerned entity, the invalidated data may be restored within the timeline of 6 months of their invalidation. Where the data referred to under sentence one is invalidated, the notified person shall not be a notified person for the operation for which the accuracy of the notified data has not been confirmed as per paragraph (2) sentence one.

(4) Data notified pursuant to Section 23 shall then be kept in the Medical Device Information System for the period of 3 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) The supply of medical devices referred to under Section 28(2) to a user who is a lay

person referred to under Art. 2(38) of the Medical Device Regulation is prohibited.

(2) Where distribution of a device onto the market within the territory of the Czech Republic is concerned, the distributor shall be obliged to supply the device together with instructions for use in the Czech language, as long as the instructions for use have been issued by the manufacturer.

Section 27

(1) For the purposes of this Act, good storage practices shall mean a suite of rules ensuring that the device transport and storage be conducted in compliance with the manufacturer´s guidance and the minimum requirements for the device safety. The minimum requirements for the device safety are defined by an implementing legal regulation.

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

PART SIX

PRESCRIBING AND DISPENSING OF DEVICES

TITLE I

DEVICE PRESCRIBING

Section 28

(1) A device shall be prescribed upon the provision of health care by a medical doctor or dentist (hereinafter referred to as the "doctor") or another healthcare professional with specialised or special professional competence as per the Act on Non-medical Healthcare Professions (hereinafter referred to as the "prescriber") on a 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-based form (hereinafter referred to as the "paper-based order"); or

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

(2) A device that may jeopardise the health or life of people even if used for the intended purpose but not under medical supervision, may be dispensed only on medical prescription issued by a doctor. The list of groups of such devices shall be stipulated by an implementing legal regulation.

(3) A device shall be issued on electronic or paper-based order also in case when the patient is entitled for its reimbursement pursuant to the act governing public health insurance[6)].

(4) An electronic or paper-based order may be used at a dispensing person´s within 30 days of its issue, unless the prescriber defines otherwise, no later, however, than within the period of one year.

(5) A paper-based order may not bear symbols or elements that hinder the readability of the completed data, data about other healthcare service providers or dispensing persons, or any promotional statements. A blank paper-based order form must not be stamped with the stamp of the healthcare service provider.

(6) An implementing legal regulation stipulates the scope of data to be shown on a paper-based order; a paper-based order shall bear data identifying the prescriber, the patient for whom the prescribed device is intended, the prescribed device and the number of pieces thereof, and the health insurance company if the device is to be reimbursed from the public health insurance system.

(7) Where the reimbursement of the device is conditioned by approval granted by the review doctor of the concerned health insurance company,

a)
the review doctor shall place a note reading “Approved by review doctor” or “Not approved by review doctor”, the date of the decision, the decision file number, signature and stamp of the deciding review doctor on the order;

b)
on the basis of the review doctor´s written approval, the prescriber shall place a note reading “Approved by review doctor”, the date of the review doctor´s decision on reimbursement approval, and the decision file number on the order; or

c)
on the basis of the review doctor´s written approval of a repeated prescription for the device, the prescriber shall place a note reading “Approved by review doctor”, the date of the review doctor´s decision on repeated reimbursement approval, and the decision file number on the order.

(8) The written approval or a document of the written approval of the review doctor referred to under paragraph (7)(b) or (c) shall be filed by the prescriber in the patient´s medical record no later than within 5 days of its delivery.

(9) Where a device the reimbursement of which is conditioned by the approval of a review doctor of 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 to the review doctor of the concerned health insurance company for endorsement by this doctor.

Section 29

Electronic order

(1) An electronic order shall be created, amended or cancelled in the ePrescription System on the basis of a request of the prescriber that shall contain the data necessary for the creation, amendment or cancellation of the electronic order. The request for electronic order creation shall, moreover, always contain information about the selected route of collection of the identification symbol of the electronic order (hereinafter referred to as the "electronic order identifier").

(2) In case of a device reimbursed from the public health insurance system, the prescriber´s request must always contain the numeric identification of the prescribed device allocated by the Institute pursuant to the Act on Public Health Insurance. A device that has not been allocated the numeric identification referred to in sentence one, may be prescribed on electronic prescription only by a doctor.

(3) If the prescriber´s request for the creation of an electronic order contains all of the required data, the ePrescription System will generate the electronic order and promptly and free of charge communicate the electronic order identifier borne by the electronic order to the prescriber. Where the patient requires that the electronic order identifier be sent thereto directly from the ePrescription System, the System shall communicate it free of charge also to the patient.

(4) The electronic order identifier shall be handed over to the patient free of charge; in the communication of the electronic order identifier, no specific healthcare service provider may be favoured and the patient´s right of choice of the dispensing person must not be hindered. Unless the patient chooses otherwise, the electronic order identifier shall be communicated thereto by means of a paper-based form. The patient may choose to have the electronic order identifier sent to him/her free of charge via another channel than the one outlined in sentence two, such channel being:

a) a data message sent to the patient´s electronic mail address using the service of the central repository of electronic orders;

b) a text message sent to the patient´s mobile telephone device using the service of the central repository of electronic orders;

c) a data message using a web or mobile application of the ePrescription System made accessible 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 service of the prescriber´s information system; or

e) a text message sent, on the basis of agreement with the prescriber, to the patient´s mobile telephone device using the service of the prescriber´s information system.

(5) Irrespective of the route of its communication, the electronic order identifier must not be accompanied by any statement of promotional nature.

(6) An implementing legal regulation stipulates:

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

b) the form of the electronic order identifier provided by the ePrescription System to the prescriber and to the patient;

c) the method of submitting requests for the creation, amendment, and cancellation of an electronic order by prescribers;

d) the scope of data necessary for the creation, amendment, and cancellation of an electronic order and particulars thereof;

e) the procedure and conditions of the provision of identification data as per Section 31(3)(b) and (4).

Section 30

Central repository of electronic orders

(1) The central repository of electronic orders is established in order to safeguard:

a) collection and storage of electronic orders;

b) collection and storage of records on the dispensing of devices on electronic orders, including information on what device was actually dispensed;

c) collection and storage of information on the handling of the electronic order.

(2) The ePrescription System shall safeguard, free of charge, the following:

a) immediate communication of the electronic order identifier to the prescriber, and, if applicable, to the patient upon request thereof;

b)

continuous access of the dispensing person to the electronic order on the basis of which the prescribed device is to be dispensed;

c)

continuous access of the prescriber to the electronic orders on which a device was prescribed thereby;

d)

continuous access of the dispensing person to the electronic orders on the basis of which a device was dispensed thereby;

e)

access of the health insurance company to electronic orders on which devices reimbursed from public health insurance were dispensed to the insureds thereof;

f)

access of the Ministry of Health to electronic orders on which devices were prescribed to persons for whom healthcare services are reimbursed by the state.

(3) The Institute, via the ePrescription System, shall process:

a)

the name(s), surname, date of birth, and address of residence of the prescriber and his/her contact data, including his/her telephone number as stipulated by an implementing legal regulation, and the identification data of the healthcare service 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, and address of residence of the person dispensing the device (hereinafter referred to as the "dispensing individual") and his/her contact data stipulated by an implementing legal regulation, and the identification data of the dispensing person, to the extent of its name, address, and contact data;

c)

patient identification data to the extent of details specified on the medical prescription;

d)

data about prescribed and dispensed devices, including their name, amount, and numeric identification of the device, if allocated by the Institute.

(4) The Institute shall store information kept in the central repository of electronic orders, including data referred to under paragraph (3), for the period of 10 years of the electronic order expiry. Following the expiry of this timeline, any information associated with such electronic order shall be removed from the ePrescription System.

Section 31

Access to the central repository of electronic orders

(1) The prescriber and the dispensing individual shall communicate with the central repository of electronic orders 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 doctor prescribing the device, and the pharmacists dispensing the device in the provision of healthcare services in a pharmacy shall access the ePrescription System by ways set forth by the Act on Pharmaceuticals.

(3) A person other than those referred to under paragraph (2) authorised to prescribe or dispense the device shall access the ePrescription System via an access certificate of the healthcare service provider within the scope of whose operation the former provides healthcare services, of an optician shop operator or 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 service provider within the scope of whose operation this person provides healthcare services, by the optician shop operator 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 the device referred to under paragraph (3) shall, moreover, access the ePrescription System also via the National Identification and Authentication Point, if the healthcare service provider within the scope of whose operation this person provides healthcare services, the optician shop operator or person with whom the health insurance company has concluded a contract on dispensing pursuant to the act governing public health insurance notify in advance the Institute of the identification data of the former by ways stipulated by an implementing legal regulation and, where the following is concerned:

a)
prescription of a device in the provision of healthcare services in the patient´s own social settings; or

b)
dispensing of a device in an optician shop or at a person with whom the health insurance company has concluded a contract on dispensing pursuant to the act governing 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 compliant with its operating documentation.

(6) The information to which access is provided for prescribers and dispensing persons via the ePrescription System may be used solely for the purposes of device prescribing and dispensing. Any other use of such data or their disclosure to third parties is prohibited.

TITLE II

DEVICE DISPENSING

Section 32

Conditions governing device dispensing

(1) Devices shall be dispensed on the basis of a medical prescription. Dispensing shall include also the provision of information necessary for the proper and safe use of the dispensed device.

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

(3) A device may be dispensed solely by a dispensing person who is a pharmacy healthcare service provider, an optician shop operator, or a person with whom the health insurance company has concluded a contract on dispensing pursuant to the act governing public health insurance. A 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) Except for risk class I devices, a device may be dispensed in a pharmacy or medical device dispensary only by

a)
a pharmacist with professional competence;

b)
a pharmaceutical assistant with professional competence; or

c)
an orthotic-prosthetic technician competent to perform the profession without expert supervision, or an orthopaedic prosthetic technician competent to perform the profession without expert supervision, where the dispensing of orthotic-prosthetic devices is concerned.

(5) A sight-correction device may only be dispensed in an optician shop. Such devices may be dispensed only by

a)
an optometrist;

b)
a qualified optician or qualified eye technician;

c)
an optician or eye technician; or

d)
an ophthalmologist.

Section 33

Mail-order device dispensing

(1) A mail-order device dispensing shall mean dispensing of a device on the basis of a paper-based or electronic order via mail-order service. Offering devices for the purposes of mail-order dispensing and the receipt of orders from persons to carry out mail-order dispensing shall be considered part of mail-order dispensing. In mail-order dispensing, the requirements governing distance sale stipulated by the Medical Device Regulation must be met.

(2) Mail-order dispensing of devices referred to under Section 28(2) is prohibited.

Section 34

Obligations of persons safeguarding mail-order dispensing of devices

In mail-order dispensing of devices, the dispensing person shall be obliged to safeguard:

a)
the publication of information on mail-order dispensing, the 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 the mail-order dispensing at its website; a mere publication of the offer shall not be considered promotion as referred to by another legal regulation[7)];

b)
that the person carrying out mail-order dispensing met the requirements set forth by Section 32(4) and (5);

c)
packaging and shipment; the dispensing person shall be responsible for maintaining the quality of the devices, even in case they contract the device shipment with another person;

d)

that shipments were sent to the ordering party no later than within the timeline published as per letter (a) or that the ordering party were forthwith informed by the dispensing person about the reasons for which delivery cannot be executed or will be executed within an extended timeline, including information about such timeline; and

e)

an information service provided by a person authorised to dispense the device during defined operating hours; such information service shall also serve for the purposes of collection and hand-over of information about the occurrence of incidents.

Section 35

Device replacement

(1) In the dispensing of a device prescribed on electronic or paper-based order, the dispensing person shall inform the patient about possible alternative options of the prescribed device and, with the patient´s consent shall be authorised to replace it with another device that is replaceable with the prescribed device in respect of performance and intended purpose. The dispensing individual shall mark the conducted replacement on the order.

(2) If the prescriber, with a view to the patient´s condition of health, or the review doctor as part of approval of the device reimbursement from the public health insurance[6)] insists on the dispensing of the prescribed device, he/she shall make a note on the paper-based order reading “Replacement not allowed” or shall tick the “Replacement not allowed” flag on the electronic order. In such a case, the dispensing person may dispense only the prescribed device.

Section 36

Excerpt from the order

If the dispensing individual, when dispensing a device on paper-based order, does not have the prescribed amount or type of the device, it shall issue an excerpt from the paper-based order for the missing device labelled as “Excerpt”. An excerpt from the paper-based order shall contain data from the original paper-based order and information on the scope of the completed dispensing. A note reading “Excerpt created” shall be made and information on the scope of the completed dispensing provided on the original paper-based order. The timeline for the validity of the excerpt from a paper-based order shall be governed by Section 28(4) analogously.

Section 37

Obligations of device dispensing persons

A dispensing person shall be obliged to:

a)

observe the rules of good storage practices;

b)

provide the patient with complete information about facts that may impact the patient´s safety and health in relation to the use of the dispensed device;

c)

store all paper-based orders and request forms for dispensed devices as referred to under Section 28(2) for the period of 5 years, unless the device was reimbursed from public health insurance;

d)

take out devices that cannot be used as per Section 38(1) and store them separately.

PART SEVEN

DEVICE USE

Section 38

General provisions

(1) A device cannot be used if it is a device:

a)

which has been placed on the market contrary to the Medical Device Regulation and the person who uses the device was aware or should have been aware and could be aware of this fact;

b)

which is reasonably suspected to jeopardise the safety and health of patients or third parties, even in case the device is properly installed or, if applicable, introduced into the human body, maintained, and used in compliance with its intended purpose[2)];

c)

whose time limit for using or implanting the device safely has expired[8)];

d)

that exhibits, in respect of its manufacture, shortcomings that could jeopardise the health of patients or third parties; or

e)

whose safety may be jeopardised or its performance compromised due to an obviously broken integrity of the original packaging.

(2) Only such medical devices that meet the requirements of the Medical Device Regulation may be used in the provision of healthcare services.

(3) If the healthcare service provider manufactures the device and uses it within the scope of healthcare services provided thereby in compliance with Art. 5(5) of the Medical Device Regulation, it shall be obliged to provide any relevant information about the device upon the Institute´s request.

Section 39

Obligations of healthcare service providers in the use of devices

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

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

b) a device with a measuring function is operated in compliance with the requirements of another legal regulation governing the area of metrology;

c) the person providing healthcare services is trained in the necessity to verify the proper technical condition, performance and possibility of safe use of the device prior to every use thereof, where such verification of the device is applicable; this requirement shall be reasonably applicable also to the accessories, software and another product which is anticipated to interact with the device in question;

d) good storage practices are observed;

e) the device is serviced in compliance with this Act;

f) where the manufacturer provided a custom-made device to the former for the purposes of healthcare service provision to a particular patient, the healthcare service provider provides the patient with the statement for the custom-made device drawn by the manufacturer pursuant to Annex XIII(1) of the Medical Device Regulation and attached by the manufacturer to the device; and

g) a field safety corrective action established by the manufacturer in order to eliminate or reduce the risk of a serious incident associated with the medical device supplied onto the market is implemented.

(2) The healthcare service provider must not use a device in the provision of healthcare services where cases referred to under Section 38(1) are concerned or where the instructions for use in the Czech language are not available thereto; this condition does not have to be met for risk class I or IIa devices in respect of which the manufacturer has established that the safe use of the device did not require instructions for use.

(3) Where a risk class IIb or III device is used in the provision of healthcare services, the healthcare service provider shall be obliged to make a record thereof to the patient´s medical documentation.

(4) The healthcare service provider shall be obliged to keep the single identification of devices supplied thereto, except for risk class I devices. Healthcare service providers shall be obliged to present this information to the Institute upon request.

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

a)
in respect of which training must be provided;

b)
in respect of which a safety technical control must be carried out; or

c)
which are considered legal measuring instruments by the legal regulation governing the area o metrology[9)].

(6) The content of the documentation of used devices as per paragraph (5) shall be stipulated by an implementing legal regulation.

Section 40

Information for device users

(1) The healthcare service provider shall be obliged to ensure that the complete information from the instructions for use in the Czech language be available to the person providing healthcare services via the device; the obligation to ensure the availability of instructions for use shall not apply to risk class I or IIa devices in respect of which the manufacturer established that the instructions for use were not necessary for the safe use of the device.

(2) The healthcare service provider responsible for the implantation of an implantable device shall be obliged to provably provide the patient whom the device was implanted or the legal guardian or carer thereof with the implant card that shall indicate the patient´s identity and information stipulated by Art. 18 of the Medical Device Regulation and shall do so in any provable manner that will allow the patient quick access to the concerned information. The information must be in the Czech language.

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

Section 41

Training

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

a)
completed training for the concerned device carried out in compliance with the concerned instructions for use; and

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

(2) The training referred to in paragraph (1)(a) may be carried out only by

a)
the manufacturer, authorised representative or person authorised thereby;

b)
persons who have been trained by a person authorised by the manufacturer or by the authorised representative to carry out such training; or

c)
a person who has completed training carried out by persons referred to under letter (a) or (b) and has at least two-year practical experience in the use of the concerned device, unless the manufacturer or authorised representative define other reservations.

(3) The healthcare service provider shall be obliged to keep and store information on all completed trainings. Such information must be kept throughout the use of the device and for the period of one year after the device decommissioning date.

Special use of a device

Section 42

(1) In cases when the life or health of a patient is jeopardised, the doctor providing healthcare services may use a device in a manner that is not in compliance with it instructions for use, unless another device of the necessary features is available thereto, providing such manner of use has been clinically verified for a similar type of device.

(2) Where the doctor intends to use the device as referred to under paragraph (1), he/she shall inform the patient or, if applicable, the patient´s legal guardian or carer to this effect and about possible consequences and risks of this course of action. If the patient´s medical condition or the absence of the legal guardian or carer does not allow the doctor to act as outlined in sentence one, the doctor shall do so as soon as practicable with a view to the patient´s medical condition or presence of the patient´s legal guardian or carer.

(3) The doctor shall make a record of the course of action taken as per paragraph (1), of the reasons therefor, and of the provision of information referred to under paragraph (2) in the

medical records kept for the patient.

Section 43

(1) Where healthcare services with the use of devices are provided following the declaration of a state of national emergency, state of war or state of emergency within the territory of the Czech Republic to soldiers on active military duty by military healthcare providers pursuant to the Act on Professional Soldiers[10)], or, if applicable, by other healthcare service professionals on the basis of a contract on the provision of healthcare services to professional soldiers concluded with a health insurance company defined by the Act on Public Health Insurance, the Ministry of Defence may adopt a course of action diverting from this Act.

(2) Where the military healthcare service providers as per the Act on Professional Soldiers[11)] provide healthcare services with the use of devices to soldiers on active military duty commissioned to fulfil tasks of the armed forces of the Czech Republic or the Military Police outside the territory of the Czech Republic[11)], the Ministry of Defence may adopt a course of action diverting from this Act.

PART EIGHT

DEVICE SERVICING

Section 44

General provisions

(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. Repairs and safety technical controls of custom-made devices shall not be considered servicing governed by this Act.

(2) Except for risk class I devices, servicing of devices may be conducted only by a notified person; this shall not apply to the course of action referred to under paragraph (3). Where a device with a measuring function is concerned, it must be serviced in compliance with another legal regulation governing the area of metrology.

(3) Where the manufacturer has provably determined that as device may be serviced only by a person authorised thereby who does not operate within the territory of the Czech Republic, the requirements set forth by Section 45(4) and (5) and Section 46(2) and (3) shall not apply to the person authorised in this manner.

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

Section 45

Safety technical control of the device

(1) A safety technical control shall mean the performance of regular actions aimed at the maintenance of safety and full functionality of the device.

(2) A safety technical control shall also include the performance of electrical control of a device that is electrical equipment. For the purposes of this Act, electrical equipment shall mean equipment that may jeopardise life, health or property by electrical current. The electrical control of the device shall be conducted in a manner prescribed by the manufacturer; where the procedure has not been defined by the manufacturer, the procedure described in technical standard governing medical electrical equipment shall be used[12)].

(3) The safety technical control shall be conducted for a device with regard to its classification into a risk class to the extent and in frequency prescribed by the manufacturer. Where the manufacturer does not define the frequency of safety technical controls of a device that is electrical equipment, the safety technical control shall be performed at least every two years. Such control must be conducted no later than in the calendar month in the course of which the timeline for the performance of the safety technical control expires.

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

a)
provably safeguard an up-to-date training of all staff performing the safety technical control by the person referred to under Section 41(2)(a) or (b) within the scope defined by the manufacturer;

b)
ensure that the safety technical control of risk class IIa, IIb and III active devices be performed solely by

1.
an employee with professional competence to conduct the profession of a biomedical technician, biomedical engineer or an orthotic-prosthetic technician;

2.
an employee who completed a university bachelor´s or master´s degree in the area of education covering machinery, technologies and materials or electrotechnology or a similar university degree obtained from a higher-education school not classified as the aforementioned area of education[13)] and with at least a three-month professional practical experience in the area of safety technical controls of devices;

3.
an employee with secondary technical education concluded by a general certificate of education or a higher technical education and at least six months of professional practical experience in the area of safety technical controls of devices;

4.

an employee with secondary education concluded by 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 completed a university bachelor´s or master´s degree in the area of education covering machinery, technologies and materials or electrotechnology or a similar university degree obtained from a higher-education school not classified as the aforementioned area of education[13)], or with secondary education concluded by a general certificate of education or a higher technical education under the direct supervision by a person referred to under point 1, 2, 3 or 4; such conduct of safety technical control of devices shall be considered practical experience for the purposes of points 2, 3, and 4;

c)
where safety technical control of a device which is electrical equipment is concerned, ensure that in addition to the requirements set forth by letters (a) and (b), the staff conducting this safety technical control also met the requirements for

1.
staff conducting independent activity as per another legal regulation governing professional competence in electrotechnology; or

2.
cognisant staff as referred to under another legal regulation governing professional competence in electrotechnology under the supervision by a person defined in point 1; and

d)
provide for adequate material and technical facilities for the conduct of the safety technical control.

(5) Following the completion of safety technical control, the servicing person must ensure that the staff performing the safety technical control draw up and sign a record thereof. Where the safety technical control is performed by a person defined under paragraph (4)(b)(5), the record shall be signed also by the person performing direct supervision. The healthcare service provider shall be obliged to keep this record throughout the use of the device as well as for the period of one year after the device decommissioning.

(6) Unless stipulated otherwise by the manufacturer, the requirements governing staff performing safety technical control shall not apply to the safety technical control performed in respect of risk class I devices without measuring function and in respect of risk class I devices which are not electrical equipment.

Section 46

Device repair

(1) A repair shall mean a set of actions through which the device´s original or operable

and safe condition is reinstated without changing the technical parameters or intended purpose thereof.

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

a)
provably safeguard an up-to-date training in the area of the concerned device repairs for all staff performing the repair by the person referred to under Section 41(2)(a) or (b) within the scope defined by the manufacturer;

b)
ensure that the repair of a risk class IIa, IIb, and III active devices be performed solely by

1.
an employee with professional competence to conduct the profession of a biomedical technician, biomedical engineer or an orthotic-prosthetic technician;

2.
an employee who completed a university bachelor´s or master´s degree in the area of education covering machinery, technologies and materials or electrotechnology or a similar university degree obtained from a higher-education school not classified as the aforementioned area of education[13)] and with at least a three-month professional practical experience in the area of device repairs;

3.
an employee with secondary technical education concluded by a general certificate of education or a higher technical education and at least six months of professional practical experience in the area of device repairs;

4.
an employee with secondary education concluded by 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 completed a university bachelor´s or master´s degree in the area of education covering machinery, technologies and materials or electrotechnology or a similar university degree obtained from a higher-education school not classified as the aforementioned area of education[13)], or with secondary education concluded by a general certificate of education or a higher technical education under the direct supervision by a person referred to under point 1, 2, 3 or 4; such conduct of device repairs shall be considered practical experience for the purposes of points 2, 3, and 4;

c)
where repair of a device which is electrical equipment is concerned, ensure that in addition to the requirements set forth by letters (a) and (b), the staff conducting this repair also met the requirements for

1.
staff conducting independent activity as per another legal regulation governing professional competence in electrotechnology; or

2.
cognisant staff as referred to under another legal regulation governing professional competence in electrotechnology under the supervision by a person defined in point 1;

d)
where repair of a device which includes a pressure mechanism is concerned, ensure that the repair of the pressure mechanism is conducted by staff who meet the requirements governing professional competence for the repairs of pressure mechanisms stipulated by another legal regulation;

e)
where repair of a device which includes a gas appliance is concerned, ensure that the repair of the gas appliance is conducted by staff who meet the requirements governing professional competence for the repairs of gas appliances stipulated by another legal regulation; and

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

(3) After the completion of the repair, the servicing person must ensure that the staff conducting the repair test the safety and functionality of the device and draw up and sign a record about the repair and testing. Where the repair is conducted by the person referred to under paragraph (2)(b)(5), the record shall be signed also by the person performing direct supervision. The healthcare service provider shall be obliged to keep this record throughout the use of the device as well as for the period of one year after the device decommissioning.

(4) Unless stipulated otherwise by the manufacturer, the requirements governing staff performing repairs shall not apply to repairs performed in respect of risk class I devices without measuring function and in respect of risk class I devices which are not electrical equipment.

Section 47

Device revision

(1) In addition to servicing, devices firmly connected to the power supply and devices including gas appliances or pressure mechanisms shall be also subjected to revisions.

(2) A revision referred to in paragraph (1) shall mean an electrical revision, pressure revision, and gas revision as referred to by other legal regulations.

PART NINE

VIGILANCE AND MARKET SURVEILLANCE

TITLE I

VIGILANCE

Section 48

Trend reporting within the scope vigilance

The Institute conducts assessment of trend reporting as per Art. 88(1) of the Medical Device Regulation. Where the results of assessment indicate a risk for the safety of patients, users or other persons or a public health risk, the Institute shall invite the manufacturer in writing to adopt adequate measures to ensure the protection of public health and patient safety and shall inform the Commission, other concerned authorities and the notified body that issued the certificate of conformity referred to under Art. 56 of the Medical Device Regulation about the result of the assessment as well as about the adopted measures.

Section 49

Serious incident record-keeping and field safety corrective actions

(1) The Institute shall keep any and all information about serious incidents that occurred within the territory of the Czech Republic, or about field safety corrective actions that were or are to be implemented within the territory of the Czech Republic, which were communicated to the Institute in compliance with the Medical Device Regulation, for the period of 15 years; in case of a serious incident associated with injury to health or death of the user, patient or another natural person, the Institute shall keep the documentation for the period of 30 years.

(2) The Institute shall keep reports of suspected serious incidents received from device users of the period of 10 years.

(3) The Institute shall assess any information communicated thereto in compliance with Art. 87 of the Medical Device Regulation and pertaining to serious incidents occurring within the territory of the Czech Republic or field safety corrective actions that were or are to be implemented within the territory of the Czech Republic together with the manufacturer, and, if applicable, the concerned notified body.

(4) Upon the delivery of the final report on the results of serious incident investigation, the Institute shall review this report with a view to ensuring the safety and health of users, patients, and other natural persons.

(5) The Institute has the right to require any documents necessary for risk assessment. Where the Institute finds out that the field safety corrective actions adopted by the manufacturer are inadequate, it shall adopt the necessary measures to ensure the safety and health or users, patients, and other natural persons and to minimise the possible recurrence of the serious incident after consultation with the manufacturer.

Section 50

Vigilance obligations of healthcare service providers

(1) The healthcare service provider with whom a serious device incident is suspected shall be obliged to

a) implement any necessary measures aimed at minimisation of the negative consequences of the arising incident;

b) provide the manufacturer and Institute access to the device in respect of which the incident is suspected, including any documentation for the purposes of control and identification of causes of the arising incident; and

c) provide the manufacturer and Institute with any necessary cooperation and information in order to establish the causes of the arising incident.

(2) A healthcare service provider who suspects that a serious incident resulting in the patient´s injury or death has arisen, shall be obliged to keep a record of this fact in the patient´s medical documentation, including a record of the date when the suspected serious incident was reported to the Institute.

TITLE II

MARKET SURVEILLANCE

Section 51

Market surveillance

(1) Where the procedure referred to under Art. 95(7) and Art. 97(2) of the Medical Device Regulation applies, the Institute shall forthwith adopt appropriate restrictive or prohibitive measures adequate to the nature of risks of supplying such device onto the market. Such measures shall be

a) restriction of the use and supply of the device onto the market in a manner adequate to the nature of the risk;

b) withdrawal of the device;

c) recall of the device.

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

Section 52

Preventive action

The Institute shall issue a decision on actions referred to under Art. 98 of the Medical Device Regulation. Appeals from such decisions shall have no suspensory effect.

PART TEN

INSPECTION AND OFFENCES

Section 53

Conduct of inspection

(1) Inspections, incl. inspections within the scope of market surveillance, shall be conducted by the Institute in compliance with the Code of Control Procedure[14)].

(2) The authorisation to conduct an inspection shall assume the form of an ID card.

Section 54

General offences

(1) A natural or legal person or a natural person-entrepreneur shall be deemed to have committed an offence by

a)
reprocessing a single-use device or supplying the reprocessed device onto the market within the territory of the Czech Republic or using such device contrary to Section 9;

b)
not observing the prohibition stipulated by Section 26(1);

c)
dispensing a device without being the authorised person referred to under Section 32(3) to (5);

d)
contrary to Art. 5(1) of the Medical Device Regulation, placing onto the market or into operation a device that does not meet the requirements of the Medical Device Regulation, or a device referred to under Art. 5(5) of the Medical Device Regulation, that does not meet general safety and performance requirements stipulated by Annex I to the Medical Device Regulation;

e)

contrary to Art. 6(1) of the Medical Device Regulation, offering through distance sale a device that does not meet the requirements of the Medical Device Regulation;

f)

contrary to Art. 6(2) of the Medical Device Regulation, using a device that was not placed onto the market, as part of business operation for the provision of a diagnostic or therapeutic service offered by means of information society services or other means of communication to a natural or legal person established within the territory of a European Union Member State, whereas such device does not meet the requirements of the Medical Device Regulation,

g)

contrary to Art. 6(3) of the Medical Device Regulation, failing to submit declaration of conformity for a device to the Institute;

h)

failing to proceed in compliance with Art. 7 of the Medical Device Regulation in respect of device labelling, provision of instructions for use, placement of devices onto the market or into operation or advertising for such devices;

i)

failing to meet any of the obligations stipulated by the manufacturer in respect of activities referred to by Art. 16(1);

j)

placing onto the market a system or procedure pack without meeting the requirements stipulated by Art. 22 of the Medical Device Regulation

k)

supplying onto the market a part referred to under Art. 23(1) of the Medical Device Regulation without ensuring that the part in question does not adversely affect the safety or performance of the device, or without keeping supporting evidence in compliance with Art. 23 of the Medical Device Regulation; or

l)

as the person liable for placing the system or procedure pack onto the market, failing to proceed in compliance with Art. 29(2) of the Medical Device Regulation.

(2) A fine for an offence may be imposed up to the amount of

a)

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

b)

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

c)

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

d)

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

e)

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

Section 55

Offences in the sphere of manufacture

(1) A device manufacturer shall be deemed to have committed an offence by

a)

contrary to Art. 10(1) of the Medical Device Regulation, failing to ensure that in the placement of devices onto the market or into operation, the devices are designed and manufactured in compliance with the Medical Device Regulation;

b)

failing to establish, document, implement or maintain a risk management system in compliance with Art. 10(2) of the Medical Device Regulation;

c)

failing to complete clinical evaluation in compliance with Art. 10(3) of the Medical Device Regulation;

d)

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

e)

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

f)

failing to draw up declaration of conformity and to place the CE mark onto the device in compliance with Art. 10(6) of the Medical Device Regulation;

g)

failing to keep the technical documentation, the EU declaration of conformity or a copy of the relevant certificates of conformity, including any amendments and annexes in compliance with Art. 10(8) of the Medical Device Regulation;

h)

contrary to Art. 10(8) of the Medical Device Regulation, failing to provide complete technical documentation or a summary thereof upon the Institute´s request, or, if their registered office is not located within the territory of a European Union Member State, failing to ensure that documentation necessary for the fulfilment of tasks stipulated by

Art. 11(3) of the Medical Device Regulation is constantly available to their authorised representative;

i) failing to establish, document, apply, maintain, constantly update, and constantly improve a quality management system in a manner ensuring that this system is compliant with the requirements set forth by Art. 10(9) of the Medical Device Regulation;

j) failing to apply or constantly update post-market surveillance system in compliance with Art. 10(10) of the Medical Device Regulation;

k) failing to ensure that information referred to under Art. 10(11) or Art. 32(1) of the Medical Device Regulation is enclosed with the device;

l) failing to meet any of the obligations stipulated by Art. 10(12) of the Medical Device Regulation;

m) not having a system for the recording and reporting of incidents and field safety corrective actions in compliance with Art. 10(13) of the Medical Device Regulation;

n) failing to submit to the Institute upon request thereof any information and documentation necessary to evidence the conformity of the device pursuant to Art. 10(14) of the Medical Device Regulation or failing to provide the required cooperation;

o) where it outsources the design or manufacture of devices with another legal or natural person, failing to provide the information about the identity of this person in compliance with Art. 10(15) of the Medical Device Regulation;

p) as a manufacturer not established within a European Union Member State, placing onto the market a device without having an appointed authorised representative in compliance with Art. 11(1) of the Medical Device Regulation;

q) concluding an agreement with the authorised representative without such agreement containing a clearly defined detailed procedure of change of the authorised representative or, where the agreement does contain such procedure, the procedure not reflecting aspects referred to under Art. 12 of the Medical Device Regulation;

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

s)

failing to provide information in respect of an implantable medical device as required by Art. 18(1) of the Medical Device Regulation;

t)
failing to update or keep a declaration of conformity in the Czech, Slovak or English language as required by Art. 19 of the Medical Device Regulation;

u)
not being able to identify the entity referred to under Art. 25(2) of the Medical Device Regulation;

v)
failing to meet any of the obligations associated with the UDI system pursuant to Art. 27 of the Medical Device Regulation;

w)
failing to enter data into the electronic system for the purposes of registration in compliance with Art. 31(1) of the Medical Device Regulation;

x)
failing to update data in the electronic system in compliance with Art. 31(4) of the Medical Device Regulation; or

y)
failing to confirm the accuracy of submitted data in compliance with Art. 31(5) of the Medical Device Regulation.

(2) A device manufacturer shall be deemed to have committed an offence by

a)
failing to draw up a justification required by Art. 61(10) of the Medical Device Regulation where a procedure pursuant to this Article is applied;

b)
not basing its post-market surveillance system as per Art. 83 on the post-market surveillance plan or by failing to ensure compliance of this plan with the requirements set forth by Annex III(1.1) of the Medical Device Regulation, or failing to keep the post-market surveillance plan as part of technical documentation for devices except for custom-made devices as per Annex II to the Medical Device Regulation;

c)
failing to implement corrective or preventive action or failing to fulfil the information duty in compliance with Art. 83(4) of the Medical Device Regulation;

d)
failing to draw up, update or provide, upon the Institute´s request, access to a post-market surveillance report for class I medical devices in compliance with Art. 85 of the Medical Device Regulation;

e)

failing to draw up, update or submit a safety report in compliance with Art. 86 of the Medical Device Regulation;

f)
failing to report a serious incident in compliance with Art. 87(1) of the Medical Device Regulation;

g)
failing to report a safety corrective action in compliance with Art. 87(1) of the Medical Device Regulation;

h)
failing to report a serious incident in compliance with Art. 87(3), (4) or (5) of the Medical Device Regulation;

i)
failing to report an incident in compliance with Art. 87(7) of the Medical Device Regulation;

j)
failing to report a trend in compliance with Art. 88(1) of the Medical Device Regulation;

k)
failing to carry out investigation associated with a serious incident in compliance with Art. 89(1) of the Medical Device Regulation;

l)
failing to provide, upon the Institute´s request, documentation for risk assessment in compliance with Art. 89(3) of the Medical Device Regulation; or

m)
failing to proceed in respect of a safety notice as required by Art. 89(8) of the Medical Device Regulation.

(3) A manufacturer of a custom-made device shall be deemed to have committed an offence by

a)
failing to draw up, constantly update or keep, for the needs of concerned authorities, documentation in compliance with Art. 10(5) of the Medical Device Regulation;

b)
failing to provide the Institute with information in compliance with Section 8(4); or

c)
failing to provide, upon the Institute´s request, a list of devices supplied by the former onto the market within the territory of the Czech Republic in compliance with Section 8(5).

(4) The manufacturer´s authorised representative shall be deemed to have committed an offence by

a) failing to provide, upon the Institute´s request, a copy of its authorisation in compliance with Art. 11(3) of the Medical Device Regulation;

b) failing to meet any of the obligations stipulated by Art. 11(3)(a) to (h) of the Medical Device Regulation listed in the authorisation, where the manufacturer is not established in any Member State of the European Union;

c) failing to provide information about the termination of its operation as the authorised representative in compliance with Art. 11(6) of the Medical Device Regulation;

d) not having a person responsible for regulatory compliance as required by Art. 15(6) of the Medical Device Regulation;

e) failing to enter in the electronic system data for the purposes of registration as required by Art. 31(1) of the Medical Device Regulation;

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

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

(5) A fine for an offence may be imposed up to the amount of

a) 200,000 CZK, where an offence referred to under paragraph (1)(t), (x) or (y), (2)(d), (3)(b) or (c) or (4)(f) or (g) is concerned;

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

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

d) 5,000,000 CZK, where an offence referred to under paragraph (1)(e), (h), (k), (n), (p), (q), (r) or (s), (2)(b), (e), (g) or (l) or (4)(d) is concerned;

e)

15,000,000 CZK, where an offence referred to under paragraph (1)(b), (i), (j), (u) or (v), (2)(c), (f), (k) or (m) or (4)(b) is concerned; or

f)

30,000,000 CZK, where an offence referred to under paragraph (1)(a), (c), (d), (g) or (l) or (2)(a) is concerned.

Section 56

Offences in the sphere of clinical investigations of devices

(1) A sponsor of a clinical investigation shall be deemed to have committed an offence by

a)

failing to conduct the clinical investigation in compliance with Art. 62(4) of the Medical Device Regulation;

b)

failing to conduct the clinical investigation in compliance with Art. 64, 65 or Art. 66 of the Medical Device Regulation;

c)

failing to ensure that the clinical investigation is conducted in compliance with Art. 72(1) of the Medical Device Regulation;

d)

failing to ensure monitoring of the conduct of the clinical investigation in compliance with Art. 72(2) of the Medical Device Regulation;

e)

failing to ensure the recording, processing or storage of any information about the clinical investigation in compliance with Art. 72(3) of the Medical Device Regulation;

f)

failing to meet the conditions of clinical investigation notification or conduct stipulated by Art. 74 of the Medical Device Regulation;

g)

making substantial changes to the clinical investigation plan without observing the procedure stipulated by Art. 75 of the Medical Device Regulation;

h)

failing to meet its information obligation upon clinical investigation suspension or termination pursuant to Art. 77(1) of the Medical Device Regulation;

i)

failing to meet its notification obligation upon termination of the clinical investigation pursuant to Art. 77(3) of the Medical Device Regulation;

j)

failing to submit a clinical investigation report or summary in compliance with Art. 77(5) of the Medical Device Regulation; or

k)

failing to report, via the electronic system, information to the concerned authorities of the Member States where the clinical investigation is conducted, as required by Art. 80(2), (3) or (4) of the Medical Device Regulation.

(2) The investigator shall be deemed to have committed an offence by

a)

failing to ensure that the clinical investigation is conducted in compliance with Art. 72(1) of the Medical Device Regulation; or

b)

failing to ensure the recording, processing or storage of any information about the clinical investigation in compliance with Art. 72(3) of the Medical Device Regulation.

(3) A fine for an offence may be imposed up to the amount of

a)

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

b)

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

c)

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

d)

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

e)

15,000,000 CZK, where an offence referred to under paragraph (1)(b), (c) or (g) is concerned; or

f)

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

Section 57

Offences in the area of device import

(1) Importers shall be deemed to have committed an offence by

a)

failing to verify whether the device has met all of the requirements set forth by Art. 13(2) of the Medical Device Regulation for the purposes of placing the device onto the market;

b)

failing to meet the information obligation as per Art. 13(2) of the Medical Device Regulation;

c)

contrary to Art. 13(2) of the Medical Device Regulation, placing a device onto the market, although they think or have a reason to think that the device does not comply with the requirements of the Medical Device Regulation;

d)

failing to provide the information laid down by Art. 13(3) of the Medical Device Regulation on the device, its packaging, or in the document enclosed with the device;

e)

failing to verify whether the device has been registered in the electronic system or failing to add their data into the said registration as per Art. 13(4) of the Medical Device Regulation;

f)

failing to safeguard the storage or transport conditions in compliance with Art. 13(5) of the Medical Device Regulation;

g)

failing to keep a registry of complaints, non-compliant devices, and cases of device withdrawals from the market and recalls or failing to provide the manufacturer, authorised representative, and distributor with data allowing to assess a complaint in compliance with Art. 13(6) of the Medical Device Regulation;

h)

failing to meet the information obligation or failing to cooperate with the manufacturer, authorised representative or Institute in compliance with Art. 13(7) of the 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;

j)

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

k)

failing to cooperate with the Institute in compliance with Art. 13(10) of the 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;

m)

failing to meet the information obligation, failing to provide a sample or mock-up of the device or failing to submit the certificate as referred to under Art. 16(4) of the Medical Device Regulation;

n)

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

o)

not being able to identify the entity referred to under Art. 25(2) of the Medical Device Regulation;

p)

failing to keep or store the UDI in compliance with Art. 27(8) of the Medical Device Regulation;

q)

failing to verify the entry of data or failing to add their data in compliance with Art. 30(3) of the Medical Device Regulation;

r)

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

s)

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

t)

failing to verify the accuracy of submitted data in compliance with Art. 31(5) of the Medical Device Regulation.

(2) A fine for an offence 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 area of device distribution

(1) Distributors shall be deemed to have committed an offence by

a)
failing to meet the notification obligation referred to under Section 23 or Section 25(1);

b)
failing to observe the prohibition referred to under Section 26(1);

c)
contrary to Section 26(2), supplying a device without its instructions for use in the Czech language;

d)
failing to observe the rules of good storage practices pursuant to Section 27(2);

e)
contrary to Art. 14(2) of the Medical Device Regulation, supplying a device onto the market, although they think or have a reason to think that the device is not compliant with the requirements laid down by the Medical Device Regulation;

f)
contrary to Art. 14(2) of the Medical Device Regulation, failing to verify compliance with the requirements set forth by this Article prior to supplying a device onto the market;

g)
failing to meet the information obligation, or failing to cooperate with the manufacturer, authorised representative or the Institute in compliance with Art. 14(2) or (4) of the Medical Device Regulation;

h)
failing to ensure storage or transport conditions in compliance with Art. 14(3) of the Medical Device Regulation;

i)

failing to keep a registry of complaints, non-compliant devices, and cases of device withdrawals from the market and recalls or failing to meet the information obligation pursuant to Art. 14(5) of the Medical Device Regulation;

j)
failing to submit, upon request of the Institute, information or documentation, failing to provide samples to the Institute or failing to cooperate with the Institute in compliance with Art. 14(6) of the Medical Device Regulation;

k)
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;

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

m)
failing to cooperate with manufacturers or authorised representatives in compliance with Art. 25(1) of the Medical Device Regulation;

n)
not being able to identify for the Institute the entity referred to under Art. 25(2) of the Medical Device Regulation; or

o)
failing to keep and store the UDI in compliance with Art. 27(8) of the Medical Device Regulation.

(2) A fine for an offence 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)(c), (f) or (k) is concerned;

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

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

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

Section 59

Offences in the area of activities of healthcare service providers

(1) Healthcare service providers shall be deemed to have committed an offence by

a) failing to report to the Institute the establishment or dissolution of an ethics committee in compliance with Section 17(1);

b) contrary to Section 17(3), failing to keep the records of the operation of the ethics committee established thereby for the required period of time;

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

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

e) failing to ensure training for the person providing healthcare services in compliance with Section 39(1)(c);

f) failing to ensure compliance with the rules of good storage practices in compliance with Section 39(1)(d);

g) failing to ensure that a device is serviced in compliance with Section 39(1)(e);

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

i) failing to make a record in medical documentation as required by Section 39(3);

j) failing to keep UDI for devices supplied thereto or failing to submit to the Institute information pursuant to Section 39(4);

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

l) failing to ensure that information is available for the person providing healthcare services in compliance with Section 40(1);

m)

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

n)

failing to ensure that a device is operated or used solely by persons who meet the conditions stipulated by Section 41(1);

o)

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

p)

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

q)

as a manufacturer of devices referred to under Art. 5(5) of the Medical Device Regulation, failing to submit, upon the Institute´s request, information in compliance with Art. 5(5) of the Medical Device Regulation;

r)

as a manufacturer of devices referred to under Art. 5(5) of the Medical Device Regulation, failing to draw up or publish, upon request, a declaration in compliance with Art. 5(5)(e) of the Medical Device Regulation;

s)

contrary to Section 50(1)(a), failing to implement necessary measures aimed at the minimisation of adverse consequences of arising incidents;

t)

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

u)

contrary to Section 50(2), failing to keep, in the patient´s medical documentation, information about suspected serious incidents and the date of reporting them to the Institute.

(2) A fine for an offence may be imposed up to the amount of

a)

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

b)

500,000 CZK, where an offence referred to under paragraph (1)(d), (e), (i), (l), (o), (p) or (u) is concerned;

c)

2,000,000 CZK, where an offence referred to under paragraph (1)(g), (k), (m), (n), (q) or (r) is concerned; or

d)

5,000,000 CZK, where an offence referred to under paragraph (1)(c), (f), (h), (j), (s) or (t) is concerned.

Section 60

Offences in the area of device dispensing

(1) Dispensing persons shall be deemed to have committed an offence by

a)

dispensing a device contrary to Section 32;

b)

breaching the prohibition set forth by Section 33(2);

c)

in mail-order dispensing, failing to meet any of the obligations set forth by Section 34;

d)

contrary to Section 35(1), in the dispensing of devices prescribed on order, replacing the device for another one with which the prescribed device cannot be replaced;

e)

contrary to Section 35(1), in the dispensing of a device prescribed on paper-based order, failing to mark the replacement on the order;

f)

contrary to Section 35(2), in the dispensing of a device, replacing the device although the order says “Replacement not allowed”;

g)

failing to observe the rules of good storage practices in compliance with Section 37(a);

h)

failing to provide the patient with the complete information pursuant to Section 37(b);

i)

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

j)

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

(2) A fine for an offence 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 area of device prescribing

(1) A legal person or a natural person-entrepreneur shall be deemed to have committed an offence by placing symbols or elements compromising the readability of the completed data, data about other healthcare service providers or dispensing persons, or advertising statements on a paper-based order contrary to Section 28(5), or by not observing the prohibition laid down in Section 29(5).

(2) A healthcare service provider shall be deemed to have committed an offence by failing to ensure the provision of the electronic order identifier to the patient contrary to Section 29(4).

(3) A prescriber shall be deemed to have committed an offence by providing the patient with an electronic order identifier for fee contrary to Section 29(4).

(4) A fine in the amount of up to 200,000 CZK may be imposed for the offences referred to under paragraphs 1 to 3.

Section 62

Offences in the area of handling of data from information systems

(1) A legal person, natural person-entrepreneur or a natural person shall be deemed to have committed an offence by providing access to or disclosing data contained in their information system to third parties contrary to Section 31(6).

(2) A fine in the amount of up to 15,000,000 CZK may be imposed for the offence referred to under paragraph (1).

Section 63

Offences in the area of device servicing

(1) Servicing persons shall be deemed to have committed an offence by

a) failing to meet the notification obligation referred to under Section 23 or Section 25(1);

b)

failing to ensure that all of the staff conducting safety technical controls are currently trained in compliance with Section 45(4)(a);

c)

failing to ensure that the safety technical control of a risk class IIa, IIb, and III active device is conducted in compliance with Section 45(4)(b);

d)

failing to ensure that the staff performing safety technical controls of a device that is electrical equipment meet the conditions stipulated by Section 45(4)(c);

e)

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

f)

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

g)

failing to ensure that all of the staff conducting repairs are currently trained in compliance with Section 46(2)(a);

h)

failing to ensure that repair of a risk class IIa, IIb, and III active device is conducted in compliance with Section 46(2)(b);

i)

failing to ensure that the staff performing repairs of a device that is electrical equipment meet the requirements stipulated by Section 46(2)(c);

j)

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

k)

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

l)

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

(2) A fine for an offence 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 64

Joint provisions governing offences

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

(2) Fines shall be collected by the Institute.

PART ELEVEN

JOINT, TRANSITORY, AND FINAL PROVISIONS

Section 65

Allowing exemptions

(1) On the basis of a request of the healthcare service provider, the Ministry may decide to authorise putting into service of a device which has not been subjected to conformity assessment procedures pursuant to the Medical Device Regulation, where

a) the use of a device for a single patient is concerned;

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

c) the use is in the interest or health of a specific patient.

(2) In compliance with the Medical Device Regulation, the Institute may, upon request of the manufacturer, authorised representative or importer, allow the placement on the market within the territory of the Czech Republic, putting into operation, and use of a specific device in respect of which the conformity assessment procedures have not been completed pursuant to the Medical Device Regulation, providing the use of the device is in the interest of public health protection, the safety or health of 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 the exemption to be allowed, including their documentation.

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

Reimbursement of costs of expert activities

Section 66

(1) The applicant shall be obliged to reimburse to the Institute the costs of expert activities conducted by the Institute upon the applicant´s request.

(2) The applicant shall be obliged to reimburse the costs of the Institute´s expert activities performed in compliance with the Medical Device Regulation or associated with

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

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

c) the preparation and conduct of training activities as referred to under Section 5(2)(l);

d) the authorisation of a clinical investigation and changes to the conditions of the clinical investigation;

e) the assessment of another clinical investigation as per Art. 82 of the Medical Device Regulation and change to the conditions of another clinical investigation as per Art. 82 of the Medical Device Regulation; or

f) the assessment of a clinical investigation as per Art. 74 of the Medical Device Regulation.

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

Section 67

(1) The person upon whose request the expert activities are to be performed shall be obliged to pay the Institute an advance payment for the reimbursement of costs if it is obvious that the expert activities will be performed. Where expert activities referred to under Section 66(2)(a) to (c) are concerned, the Institute shall publish the usual amount of time necessary for the completion of the individual activities on its website.

(2) The Institute shall refund the reimbursement of costs to the applicant upon the latter´s request

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

b) in full amount if the required expert activity has not been commenced; or

c) in the amount corresponding to the pro rata amount of the paid reimbursement of costs of expert activities that have not been performed.

(3) The applicant shall pay the difference between the advance payment for the reimbursement of costs as referred to under paragraph (1) and the actual amount of reimbursement of costs where the actual amount of reimbursement of costs is greater than the advance payment, and shall do so within the timeline stipulated by the Institute in the invitation to pay the balance of reimbursement of costs.

(4) Reimbursement of costs referred to under Section 66 shall not be a state budget income as per another legal regulation, but the income of the Institute and shall be kept at a special account forming part of the Institute´s reserve fund. The Institute shall use such funds to safeguard its operation pursuant to this Act or to other legal regulations, where such operation cannot be covered from budgetary funds in the necessary scope.

(5) Where the government decides so, the Institute shall transfer an amount defined by the government from the account kept as per paragraph (4) to the income account of the state budget of the Czech Republic opened for the Ministry of Health.

Section 68

Enabling provision

The Ministry shall issue a decree implementing Section 13(3) and (4), Section 27(1), Section 28(2) and (6), Section 29(6), Section 31(4), Section 39(6), and Section 66(3).

Transitory provisions

Section 69

(1) Legal relationships to which existing legal regulations apply in compliance with the Medical Device Regulation, shall be governed by the existing legal regulations.

(2) Distributors, servicing persons or manufacturers of custom-made devices who notified their operation pursuant to Act No 268/2014 Coll., on Medical Devices and on Amendment to Act No. 634/2004 Coll., on Administrative Fees, as amended, in the version applicable prior to the coming into force of this Act, shall be considered persons who

complied with their notification obligation in compliance with Section 8 or 23. The date of coming into force of this Act shall be considered the date of notification.

(3) The data referred to under Section 23(2)(c)(1) and Section 23(2)(d)(1) shall be notified by the distributor or device servicing person only at the moment when the information required by this Act is available in the Eudamed database, no later, however, than within 3 months of the date of their publication in the Eudamed database. Until the notification of the data referred to in Section 23(2)(c)(1), the distributor shall notify the business name and generic group of the device[15)].

(4) A device that has been put into service prior to the date of coming into force of this Act and that has been properly CE marked or properly labelled with the Czech conformity mark[16)] may be used in the provision of healthcare services in case it is being serviced in compliance with this Act.

(5) A device may be dispensed on medical prescription issued prior to the date of coming into force of this Act pursuant to Act No 268/2014 Coll., as amended, in the version effective prior to the date of coming into force of this Act.

Section 70

(1) In case of training referred to under Section 41(2), in respect of a product the manufacturer of which has been already dissolved, the manufacturer´s instruction may be replaced with instruction by a person who has at least three years of practical experience in the use of the concerned device type.

(2) A person who has at least one-year practical experience in the area of the conduct of device safety technical controls as of the date of coming into force of this Act shall be considered a person meeting the requirement for professional qualification as per Section 45(4)(b). A person who has at least one-year practical experience in the area of the conduct of repairs of the concerned device or a similar device type as of the date of coming into force of this Act shall be considered a person meeting the requirement for professional qualification as per Section 46(2)(b).

(3) In respect of a safety technical control as referred to by Section 45 or repair as per Section 46, for a device whose manufacturer has been dissolved, it shall be possible to replace the training pursuant to Section 45(4)(a) or training pursuant to Section 46(2)(a) with training by a person who has at least five-year practical experience in the servicing of the concerned device type.

Section 71

(1) The Institute shall conduct inspections of ongoing clinical investigations authorised pursuant to Act No 268/2014 Coll., as amended, in the version effective prior to the date of coming into force of this Act and initiated prior to the date of coming into force of this Act pursuant to Act No 268/2014 Coll., as amended, in the version effective prior to the date of coming into force of this Act.

(2) Incident investigations notified to the Institute in compliance with the current legal

regulations shall be completed pursuant to Act No 268/2014 Coll., as amended, in the version effective prior to the date of coming into force of this Act.

(3) The monitoring of implementation of safety corrective actions notified to the Institute in compliance with existing legal regulations shall be completed in compliance with Act No 268/2014 Coll., as amended, in the version effective prior to the date of coming into force of this Act.

Section 72

(1) Procedures regarding the authorisation of a clinical investigation filed via the Medical Device Registry in compliance with Act No 268/2014 Coll., as amended, in the version effective prior to the date of coming into force of this Act, pending as of the date of coming into force of this Act, shall be stopped.

(2) Clinical investigations authorised in compliance with Act No 268/2014 Coll., as amended, in the version effective prior to the date of coming into force of this Act, but not initiated prior to the date of coming into force of this Act shall be considered unauthorised.

(3) In the conduct of clinical investigations authorised in compliance with Act No 268/2014 Coll., as amended, in the version effective prior to the date of coming into force of this Act and initiated prior to the date of coming into force of this Act, procedures outlined by existing legal regulations shall be followed.

(4) Clinical investigations referred to under Art. 82 of the Medical Device Regulation planned or initiated in the period from the date of coming into force of this Act and the putting into operation of the Medical Device Information System shall be notified by the sponsor via the Medical Device Information System without unnecessary delay as soon as the System is put into operation.

Section 73

(1) The Institute shall establish the Medical Device Information System no later than within 18 months of the coming into force of this Act or within 6 months of the date of putting Eudamed into operation, whichever occurs later.

(2) The Institute shall be obliged to organise the forwarding of all data notified by the custom-made device manufacturer, distributor or device servicing person in compliance with Act No 268/2014 Coll., as amended, to the Medical Device Information System no later than within 6 months of putting the Medical Device Information System into operation.

(3) Until the establishment of the Medical Device Information System, the Medical Device Register established in compliance with Act No 268/2014 Coll., as amended, shall be used for the fulfilment of obligations set forth by Sections 23 to 25.

Section 74

(1) Until the full functionality of the clinical investigations module of the Eudamed database, the reporting of serious incidents arising in the course of clinical investigations of medical devices as per Art. 123(3)(d) of the Medical Device Regulation shall be conducted in compliance with Act No 268/2014 Coll., as amended, in the version effective prior to the date of coming into force of this Act.

(2) Until the full functionality of the clinical investigations module of the Eudamed database, the Medical Device Register established in compliance with Act No 268/2014 Coll., as amended, in the version effective prior to the date of coming into force of this Act, shall be used for applications for clinical investigations as per Art. 62 and Art. 74(2) of the Medical Device Regulation.

(3) Until the full functionality of the clinical investigations module of the Eudamed database, the Medical Device Register established in compliance with Act No 268/2014 Coll., as amended, in the version effective prior to the date of coming into force of this Act shall be used for the registration of clinical investigations and submission of applications for changes to clinical investigations authorised pursuant to existing legal regulations.

(4) Until the full functionality of the persons module of the Eudamed database, persons shall be registered in compliance with Act No 268/2014 Coll., as amended, in the version effective prior to the date of coming into force of this Act.

(5) Until the full functionality of the medical device module of the Eudamed database, medical devices shall be notified in compliance with Act No 268/2014 Coll., as amended, in the version effective prior to the date of coming into force of this Act.

(6) Until the issuance of individual serious incident or suspected serious incident report forms as per Art. 91 of the Medical Device Regulation, in compliance with Art. 123(3)(d) of the Medical Device Regulation, reports shall be submitted in the scope defined by Act No 268/2014 Coll., as amended, in the version effective prior to the date of coming into force of this Act.

Section 75

The provisions hereof applicable to electronic orders shall not be applied until the first day of the second calendar month following the date of publication of communication announcing that the central repository of electronic orders has been put into operation. The communication announcing that the central repository of electronic orders has been put into operation shall be published by the Ministry of Health in the Collection of Acts.

Section 76

Technical regulation

This Act has been notified 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

Repeals

The following is being repealed:

1. Government Order No 54/2015 Coll., on technical requirements for medical devices;

2. Government Order No 55/2015 Coll., on technical requirements for active implantable medical devices.

PART TWELVE

Amendment to the Act on Pharmaceuticals

Section 78

Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (Act on Pharmaceuticals), as amended by Act No 124/2008 Coll., Act No 296/2008 Coll., Act No 141/2009 Coll., Act No 281/2009 Coll., Act No 291/2009 Coll., Act No 75/2011 Coll., Act No 375/2011 Coll., Act No 50/2013 Coll., Act No 70/2013 Coll., Act No 250/2014 Coll., Act No 80/2015 Coll., Act No 243/2016 Coll., Act No 65/2017 Coll., Act No 66/2017 Coll., Act No 183/2017 Coll., Act No 251/2017 Coll., Act No 36/2018 Coll., Act No 44/2019 Coll., and Act No 262/2019 Coll., shall be amended as follows:

1. In Section 81(1), at the end of letter (f), the word “and” shall be replaced with a semicolon.

2. In Section 81, at the end of paragraph (1), the full stop shall be replaced with the word “and”, and letter (h) shall be added and shall read, incl. footnote 117, as follows:

"h) Central repository of electronic orders pursuant to another legal regulation[117)].

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117) 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.".

3. In Section 81(4)(a), the words “surname and” shall be replaced with the word “surname”, and the words “and the address of residence” shall be added after the word

“birth”.

4. In Section 81(4)(b), the words “surname and” shall be replaced with the word “surname”, and the words “and the address of residence” shall be added after the word “birth”.

5. In Section 81a(1), the following sentence shall be inserted after sentence one: “The access data of the doctor and pharmacists as per sentence one may be replaced with identity evidence obtained from the national Identification and Authentication Point[118)].” and the following sentence shall be inserted after sentence three: “The ePrescription System shall be accessed also by other persons, if stipulated by another legal regulation[118)].”.

Footnote no. 118 shall read:

“118)
Act No 250/2017 Coll., on Electronic Identification, as amended.”.

PART THIRTEEN

ENTRY INTO FORCE

Section 79

This Act enters into force on 26 May 2021.

Vondráček, in his own hand
Zeman, in his own hand
Babiš, in his own hand

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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

2) 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.

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

4) Art. 2(12) of the Medical Device Regulation.

5)

Art. 30 of the Medical Device Regulation.

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

7) Act No 40/1995 Coll., an Advertising Regulation, as amended.

8) Annex I(III)(23.2)(i) of the Medical Device Regulation.

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

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

11) Art. 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 Amendments to Some Acts (Military Police Act), as amended.

12) ČSN EN 62353 - Zdravotnické elektrické přístroje - Opakované zkoušky a zkoušky po opravách zdravotnických elektrických přístrojů. (Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment)

13) Annex 3 to Act No 111/1998 Coll., on Higher Education Institutions and on Amendment to Other Acts (Higher Education Act), as amended.

14) Act No 255/2012 Coll., on Control (Code of Control Procedure), as amended.

15) Art. 2(7) of the Medical Device Regulation.

16) Act No 22/1997 Coll., as amended.
Government Regulation No 179/1997 Coll., laying down the graphic appearance of the Czech conformity mark, its execution and affixing on the product, as amended.