Medical Devices - CZECH REPUBLIC

Competent authority

Contact Details	**Contact Name 1** State Institute for Control of Drugs-/ Státní ústav pro control léčiv (SÚKL) **Phone** +420 272 185 111 **Fax** +420 271 732 377 **Email General** posta@sukl.cz **Address** Šrobárova 48 **ZIP/City** 100 41 Praha 10 **Country** Czech Republic (CZ) **Web address** http://www.sukl.eu/ **Additional Information** No local CA.
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** Competent Authority/-ies (CA)/ For certain types of MDs Ethics committee(s) **CA - Submission for authorisation mandatory for** MD CE-marked, use outside label MD CE-marked, use outside label + IMP MD without label MD without label + IMP **CA - Registration/ notification without approval required for** – **CA - Submission required to** National CA **CE-marked MD used within label are exempted from any notification obligation to CA** Yes **Applicable national legal framework/ Reference** Section 14 of Act No 268/2014 Coll. on Medical Devices **Submission to CA and EC to be performed in the following order** EC first

Submission of Application	**Responsible for study submission** Sponsor Manufacturer acting as sponsor Legal representative **Entitled to study submission** – **Prerequisites for submission** Written approval of the ethics committee **Applicable national legal framework/ Reference** Section 14 & 21 of Act No 268/2014 on MD
Submission Format	**Format option(s)** Electronically Via the Registry of Medical Devices (RZPRO) **Preferred format** – **Online portal** http://www.sukl.eu/medical-devices/launch-of-the-new-registry-of-medical-devices-rzpro **Standard application form available** Yes **Standard application form** Standard Clinical Investigation Notification Forms for MD and AIMD (active implantable MD) are available on the SÚKL website in Czech and English: Medical Devices / Clinical evaluation of medical devices / Guidelines and Forms **Guidance on submission format** Related details are available on SUKL website in section: Medical Devices / Clinical evaluation of medical devices / Application for authorisation of clinical investigation conduct. The required contents of clinical investigation dossier specified in Section 21 of Act No 268/2014 on Medical Devices **Applicable national legal framework/ Reference** Section 15 and 21 of Act No 268/2014 on Medical Devices
Language of Submission	**Language(s) of application** Czech **Preferred language of application** – **English accepted** Yes **Documents mandatory to be in official national language** – **Documents mandatory to be in local language of study site** – **Documents mandatory to be in language of the study participant** –

Submission Fees	**Fees for trial submission mandatory** Yes **Fees** Notification of operation of a sponsor of a clinical investigation on a medical device: 2 500 CZK Application for medical device clinical investigation authorization: 500 CZK Expert activities associated with the issue of authorisation of conduct of a clinical investigation on a medical device: 15 000 CZK Expert activities associated with the issue of authorisation of changes to the conditions of a clinical investigation on a medical device: 1 500 CZK If the sponsor is non commercial subject and ask the SUKL for a fee waiver, it is possible to get the assessment for free. **Waiver for academic (non-commercial) studies possible** Yes **Official guidance on required fees** The amount of costs of expert services is set forth by an implementing legal regulation, Decree No 61/2015 Coll., on determination of the amount of reimbursement for expert activities conducted by the State Institute for Drug Control pursuant to the Act on Medical Devices, of 31 March 2015. Fees are also specified on SUKL website in section: Medical Devices / Clinical evaluation of medical devices / Fees associated with clinical investigation authorization. **Applicable national legal framework/ Reference** Decree No 61/2015 Coll
Timelines Authorisation	**General timespan (max nr days)** 60 **Mode of approval (General)** Explicit In case the CA fails to issue its decision within the timeline, the conduct of the clinical investigation shall be considered authorised **Timespan counted from** Date of submission of valid application **Applicable national legal framework/ Reference** Section 15 of Act No 268/2014 on Medical Devices
Amendments/ Substantial Amendments (SA)	**Notification mandatory for** – **Authorisation mandatory for** Any changes to the conditions of the clinical investigation/ clinical investigation plan **Responsible for submission of SA** Sponsor **Timeline for approval of SA (max nr days)** 30 In case that the CA does not provide its decision within the specified timeline, the changes shall be considered approved thereby.

Applicable national legal framework/ Reference

Section 15 of Act No 268/2014 on Medical Devices

Additional Information

The proposed changes in the clinical investigation dossier and a written approval of the proposed changes by the ethics committee shall be submitted to the CA.

Safety Reporting

Responsible for AE reporting to CA

Sponsor

Sponsor must declare reportable events to

Competent Authority
Relevant EC(s)
Investigators shall also be notified

Reportable AEs

SAE (Serious Adverse Event) arising from the testing of the MD

SUSAR being life-thereatening or leading to death must be reported

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All other SUSARs

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SAE /SADE must be reported

Immediately

National standard reporting form available

Yes
European standard SAE reporting form MEDDEV 2.7/3 to be used

Standard Reporting Form

Serious Adverse Event Reporting Form: Electronically completed and signed with a certified electronic signature in the Czech or English language.

Reporting format - Options

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Preferred format

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Provision of Annual safety report mandatory

Yes

Annual safety report shall be provided by sponsor to

National CA
Relevant EC(s)
(no later than by 31 January of the following year)

Guidance on AE reporting procedure

Related details are available on the SUKL website in section: Medical Devices / Clinical evaluation of medical devices / Serious Adverse Event (SAE) reporting. The particulars of Serious Adverse Event reporting to the Institute are set forth by Section 2 of Decree No 62/2015 Coll., implementing some provisions of the Act on Medical Devices.

Applicable national legal framework/ Reference

Section 19 of Act No 268/2014 on Medical Devices
Section 2 of Decree No 62/2015

Additional Information

(1) Where the clinical investigation is conducted using also medical devices for which conformity has been assessed (which are CE-marked) and during their use an event occurred which resulted or could result in a serious deterioration of the state of health or death, such events shall be reported as adverse incidents in compliance with Section 70 of the Act on Medical Devices.

(2) SAE reporting obligations in a clinical investigation of a MD commenced prior to the effective date of the new Act on Medical Devices and uncompleted by this date: Requirements specified on SUKL website in section: Medical Devices / Clinical evaluation of medical devices / Serious Adverse Event (SAE) reporting.

Investigator shall report SAE to

Sponsor

Reporting timeline

Immediately

Sponsor is obliged to notify all investigators of SAE/ SADE occurrence

Yes

End of Trial

End of trial declaration mandatory for

All clinical investigations requiring authorisation by CA

Responsible for End of trial declaration

Sponsor

Regular Termination - Declaration timespan (max nr days)

30

Timespan counted from

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Early/premature Termination - Declaration timespan (max nr days)

30

Reasons for early termination shall be clearly stated

Yes

Applicable national legal framework/ Reference

Section 19 of Act No 268/2014 on Medical Devices

Ethics committee

Contact Details

Contact Name 1

ECs for clinical investigations with MD, established at health care facilities + Multi-centric Ethics Committees (MECs)

Contact Name 2

A register is provided on the SUKL (State Institue for Drug Control) website

Web address

http://www.sukl.eu/sukl/ethics-committee-established-at-healthcare-facilities

Ethical Review – General	**Submission for Ethical review mandatory for** Observational MD investigations MD CE-marked, use within label MD CE-marked, use within label + IMP MD CE-marked, use outside label MD CE-marked, use outside label + IMP MD without label MD without label + IMP **Submission to CA and EC to be performed in the following order** EC first **Additional Information** No parallel request for authorisation possible: there is a need of an EC opinion before submission to the CA **Regulatory and ethics bodies involved in approval process** Competent Authority/-ies (CA)/ For certain types of MDs Ethics committee(s)
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** Local EC linked to the trial site **Additional Information** Single-centre studies are submitted to an EC set up by the health care provider on whose site the clinical investigation will be carried out. The EC gives written consent to the conduct of clinical trials of a MD and oversees their progress in terms of safety and respect for the rights of subjects. For this purpose, it assesses the competence of examiners, including the principal investigator, the appropriateness of the equipment, procedures, and selected groups of subjects, independently of the authorities, investigators and administrative or other authorities.
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Multicentric Ethics Committee (MEC) + all local ECs of involved trial sites **Submission of application required to** Multicentric Ethics Committee (MEC) + all local ECs of involved trial sites **Additional Information** Applications for opinions on multicentric clinical trials have to be submitted to one of the11 established Multicentric Ethics Committees (MECs) and, concurrently, to all local ECs at the planned trial sites. The applicant needs to inform all relevant ECs on the involvement of other ECs (multicentric about local and vice versa). The multisite clinical trial ethical review is done by an ethics committee for multi-site studies (MEC) and also by each of the relevant local EC.
Submission of Application	**Responsible for study submission** Sponsor **Entitled to study submission** – **Prerequisites for submission / approval** – **Guidance on study submission** The required documentation accompanying the application is set forth by Section 21(a) except for items 5 and 6 of the Act on Medical Devices

	Applicable national legal framework/ Reference Section 17 & 21 (a) of Act No 268/2014 on Medical Device
Submission Format	**Format option(s)** Paper hardcopy Electronically **Preferred format** – **Standard application form** Notification shall be in writing. **Applicable national legal framework/ Reference** Section 17 of Act No 268/2014 on Medical Devices
Language of Submission	**Language(s) of application** Czech **Preferred language of application** – **English accepted** Partly, not for all documents **Documents mandatory to be in official national language** Information material, Documents and Forms intended for study participants and patient information **Documents mandatory to be in local language of study site** – **Documents mandatory to be in language of study participant** –
Submission Fees	**Fees for Ethical review mandatory** Yes **Waiver for academic (non-commercial) studies possible** Yes **Fees for Ethical review** Fees for evaluation (in CZK -VAT included) EC in role of MEC: Multicentric clinical trial (up to 10 centers): 48 000 CZK For every center : 6 000 CZK For every additional center (from 11th site) : 4 800 CZK Evaluation of amendments: 6 000 CZK EC acting as LEC in a multicentric study: Approval for a single local study site: 12 000 CZK Monocentric study: 24 000 CZK (if study is extended to other sites and EC takes over the function as MEC: + 24 000 CZK) Evaluation of revised application: 6 000 CZ
Timelines Ethical Review	**General timespan for single-centre studies (max nr days)** 60 **General timespan for multi-centre studies (max nr days)** 60

	External expert advice required: Timespan (max nr days) – **Clock-stop possible if complementary information requested** Yes **Timespan counted from** Date of submission of valid application **Applicable national legal framework/ Reference** Section 17 of Act No 268/2014 on Medical Devices
Amendments/ Substantial Amendments (SA)	**Ethical review mandatory for** Any changes to the conditions of the clinical investigation/ clinical investigation plan **Responsible for notification of SA** – **Timeline Ethical review of SA (max nr days)** – **Applicable national legal framework/ Reference** Section 19 of Act No 268/2014 on Medical Devices
Safety Reporting	**Reportable AEs** AE (Adverse Event) SAE (Serious Adverse Event) arising from the testing of the MD **Investigator shall report SAE to** Sponsor **Reporting timeline** Immediately **Responsible for AE reporting to relevant EC(s)** Sponsor **SUSAR being life-thereatening or leading to death must be reported** – **All other SUSAR must be reported** – **SAE/SADE must be reported** Immediately **Sponsor is obliged to notify all investigators of SAE/ SADE occurrence** Yes **National Standard Reporting form available** – **Reporting format - Options** – **Preferred reporting format** –

	Provision of Annual safety report mandatory Yes **Applicable national legal framework/ Reference** Section 19 of Act No 268/2014 on Medical Devices Section 2 of Decree No 62/2015 **Additional Information** Annual safety report: shall be provided no later than by 31 January of the following year
End of Trial	**End of trial Declaration mandatory** Yes **Responsible for End of trial Declaration** Sponsor **Regular Termination - Declaration timespan (max nr days)** 30 **Timespan counted from** – **Early/premature Termination - Declaration timespan (max nr days)** 30 **Reasons for early termination shall be clearly stated** Yes **Applicable national legal framework/ Reference** Section 19 of Act No 268/2014 on Medical Devices
Additional Information & Specifics	**Additional Information** An ethics committee may be established by a provider of healthcare services from whom the sponsor of the clinical investigation has ordered its conduct. On the basis of a written contract concluded with a provider of healthcare services who has not established it, any ethics committee may act also as the ethics committee for this provider of healthcare services. The conditions for the operation of the ethics committee shall be safeguarded by the provider of healthcare services who has established the committee. The provider of healthcare services shall notify the Institute of the establishment of an ethics committee, including its membership, within the timeline of 30 days of its establishment. Dissolution of an ethics committee shall be notified to the Institute by the provider of healthcare services without any delay. (Section 16 of Act No 268/2014 on Medical Device)

Study specific Requirements

Sponsor	**Sponsor - Definition available in national law** Yes **Sponsor - Definition (pursuant to national law)** Sponsor of the clinical investigation (pursuant to Section 13 of Act No 268/2014 Coll. on Medical Devices): 'the person who orders the conduct of the clinical investigation from a provider of healthcare services, and who safeguards the commencement, management, organisation, control, and, where applicable, financing of the clinical investigation. The sponsor of the clinical investigation shall be established within the territory of a Member State or shall grant the power of attorney to a person established within the territory of a Member State'

	Sponsorship mandatory Yes **Sponsorship mandatory - Additional information** It is mandatory to have a sponsor in interventional investigations on MD (CE-marked, used within or outside label + non-CE-marked devices + respective combination studies with MP) and observational investigations on MD. **Co-Sponsor - Definition available in national law** No **Legal representative based in the EU/EEA is mandatory where Sponsor is located outside EU/EEA:** Yes **Additional Information** Obligations of the sponsor of a clinical investigation are specified in Section 19 of Act No 268/2014 Coll. on Medical Devices.
Investigator	**Entitled to be principal investigator** – **Additional Information** Investigator (pursuant to Section 13 of Act No 268/2014 Coll. on Medical Devices): 'a medical professional with adequate expert and specialised qualification, appointed by the sponsor of the clinical investigation who safeguards the course of the clinical investigation conducted within a single professional workplace' Principal investigator (where a multicentric clinical investigation is concerned): 'a medical professional with adequate expert and specialised qualification, appointed by the sponsor of the clinical investigation who is responsible for the coordination and course of the multicentric clinical investigation' Obligations of the investigator/Principal Investigator of a clinical investigation are specified in Section 20 of Act No 268/2014 Coll. on Medical Devices.
Study Participants - Informed Consent (IC)	**Standard IC form (ICF) available** Not specified **IC is regulated by law** Yes **Informed Consent - Definition/ Requirements** Definition: 'a voluntary and provable expression of the will of the person who is to become a trial subject, or his/her guardian or custodian, to undergo the clinical investigation, confirmed by the signature of the trial subject or, where applicable, his/her guardian or custodian.' Definition and specific requirements are provided in Section 18 of Act No 268/2014 Coll. on Medical Devices **Applicable national legal framework/ Reference** Section 18 of Act No 268/2014 Coll. on Medical Devices
Study Participants - Vulnerable Population	**Minors / Children - Studies allowed** Yes Special provisions apply

Specific provision

a) the intended purpose of the investigational medical device is prevention against a serious disease, determination of diagnosis or improvement of a serious medical condition of such trial subjects; and
b) the clinical investigation would not provide satisfactory results in trial subjects older than 18 years of age. (Section 14(3) of Act No 268/2014 Coll. on Medical Devices)
Specific requirements regarding Informed Consent are covered by Section 18(6) of this Act.

Legal framework/Reference (Minors/Children)

Section 14(3) & 18(6) of Act No 268/2014 Coll. on Medical Devices

Incapacitated persons - Studies allowed

Yes
Special provisions apply

Specific provisions

For inclusion of Partially legally incapacitated trial subjects:
a) the intended purpose of the investigational medical device is prevention against a serious disease, determination of diagnosis or improvement of a serious medical condition of persons with the same disease or medical handicap;
b) the clinical investigation, if conducted in subjects with another diagnosis or subjects with full legal capacity would not render satisfactory results; and
c) the conduct of the clinical investigation poses only a slight risk for the person with the given medical condition. (Section 14(5) of Act No 268/2014 Coll. on Medical Devices)

Specific requirements regarding Informed Consent are covered by Section 18(7) of this Act.

Legal framework / Reference (Incapacitated persons)

Section 14(5) & 18(7) of Act No 268/2014 Coll. on Medical Devices

Emergency situations - Studies allowed

Yes
With limitations

Emergency situation without prior consent of patient or proxy - Studies allowed

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Conditions allowing trial participation in emergency setting without prior consent

If, with a view to his/her state of health, the trial subject is unable to grant informed consent prior to the commencement of the clinical investigation, which aims at the trial subject’s direct benefit, he/she shall provide his/her written consent at the time he/she is informed about the nature, significance, impacts and risks of the clinical investigation. In such a case, the inclusion of the trial subject in the clinical investigation shall be conditioned by the execution of a record of this fact in the medical records kept about the patient, which shall be signed by the investigator and a witness. (Section 18(8) of Act No 268/2014 Coll. on Medical Devices)

Legal framework / Reference (Emergency Situation)

18(8) of Act No 268/2014 Coll. on Medical Devices

Pregnant or breastfeeding women - Studies allowed

Yes
Special provisions apply

Specific provisions

a) the intended purpose of the investigational medical device is prevention against a serious disease,
non-official translation
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determination of diagnosis or improvement of a serious medical condition of pregnant or lactating women or unborn children;
b) the conduct of the clinical investigation poses only a slight risk for the unborn child or infant; and c) there is a justified presumption that satisfactory results of the clinical investigation may be achieved only in case a pregnant or lactating woman participates therein.

Legal framework / Reference (Pregnant or breastfeeding women)

Section 14(4) of Act No 268/2014 Coll. on Medical Devices

Data Protection

Notification to DP Authority/ Ombudsmann is mandatory

No

Specific notification timelines before operations start

–

Language of notification

–

Notification format

–

Data Protection Authority/ Agency - Contact Details

The Office for Personal Data Protection

Phone

+420 234 665 111

Fax

+420 234 665 444

E-Mail

posta@uoou.cz

Web address

https://www.uoou.cz/en/

Address

Pplk. Sochora 27

ZIP/City

170 00 Praha 7

Country

Czech Republic (CZ)

Additional Information

Legislation:
Act No. 101/2000 Coll., on the protection of personal data (2000)

Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)

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Insurance	**Liability insurance or alternative arrangements for damages mandatory for** – **Responsible for covering insurance** Sponsor **Applicable national legal framework/ Reference** Section 14(2) & 19(2) of Act No 268/2014 Coll. on Medical Devices **Additional Information** Insurance must cover any damage, injury to health or death, effective throughout the conduct of the clinical investigation including cases when it is not possible to evidence the fault of a specific person; the scope of insurance shall be adequate to the risks associated with the conducted clinical investigation
Archiving & Data Management	**Study documents must be kept at least (in years)** 15 **Applicable national legal framework/ Reference** Section 21(2) Act No 268/2014 Coll. on Medical Devices **Additional Information** The provider of healthcare services shall keep the clinical investigation dossier for the period of at least 15 years of the termination of the clinical investigation.

National legislation

General Information: Applicable Legislation & Conventions	**Official website providing relevant national legislation available** Yes **Official website providing relevant national legislation** (1) SUKL - State Institute for Drug Control (Section: Medical Devices / Legislation) (2) Ministry of Health (Ministerstvo zdravotnictví) provides information on legal provisions regulating the field of medical devices
Investigations on Medical Devices	**Applicable national regulations** National Act on Medical Devices Other **Act on Medical Devices (or comparable national legal framework)** Act No. 268/2014 Coll. on Medical Devices and on Amendments to Act No 634/2004 Coll., on Administrative Fees This Act is a complex legal regulation which covers issue of Medical devices in the Czech Republic. It came into effect on the First of April, 2015. Decree No. 62/2005 Coll., implementing certain provisions of the Act on Medical Devices (came into effect on the Third of April, 2015). Section 11 provides provisions about vigilance – Suspected adverse incident reporting and adverse incident reporting

Other applicable regulations / implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)

- Decree No. 61/2015 Coll. that lays down amount of reimbursement of costs of expert activities executed by the State Institute for Drug Control under the Act on Medical Devices

Act No. 22/1997 Coll. on technical requirements on products and on changes and amendments of some Acts, in wording of later rules:
- Government Regulation No. 54/2015 Coll., about technical requirements on medical devices
- Government Regulation No. 55/2015 Coll., about technical requirements on active implantable medical devices
- Government Regulation No. 56/2015 Coll., about technical requirements on in vitro diagnostic medical devices

Radiation & Radiotherapy

Use of radiation or radioactive compounds - Specific requirements

Yes

Applicable legal framework

Radiation Act No.18/1997 and its implementing legislation must be regarded if devices emitting radiation are used.

Definition

MD/MD Investigation

MD - Definition available in national law

Yes

MD - Definition

Definitions for different types of Medical Devices are provided in Secton 2 & 3 of Act No 268/2014 Coll. on Medical Devices
e.g '(2) Medical device intended for clinical investigation shall mean any device intended for use by a duly qualified medical practitioner exclusively for the conduct of its own efficacy and safety in the course of a clinical investigation in adequate human clinical environment.'

Investigation of MD - Definition available in national law

Yes

Investigation of MD - Definition

Clinical investigation (pursuant to Section 11(4) of Act No 268/2014 Coll. on Medical Devices):
'the use of the medical device in a trial subject in the process of systematic testing at the premises of a provider of healthcare services with the objective to
a) evidence whether the tested medical device is suitable for use in compliance with the intended purpose, particularly in respect of safety and efficacy;
b) establish the influence of the medical device upon the trial subject; and
c) specify the side effects of the tested medical device and evaluate whether they represent acceptable risks.'