Questionnaire for the Submitted Clinical Investigation of a Medical Device

1 Questions Related to the Protocol

1.1 Full title of the clinical investigation in Czech, including acronym:

1.2 Protocol number:

1.3 EUDAMED number:

1.4 Objective of the clinical investigation (How will the clinical investigation contribute to diagnostic and therapeutic practice, medical knowledge, or what benefit will it bring to the individual subject of the investigation)**:**

1.5 The clinical investigation is *(tick as appropriate)**:***

a) Conduct of a clinical investigation of a medical device pursuant to Act No 375/2022 Sb., on medical devices and in vitro diagnostic medical devices, as amended
b) Funded from own resources / by a professional organisation / company
c) Has a different nature (please specify):

1.6 Study design *(tick as appropriate)**:***

a) Randomisation
b) Blinding
c) Prospective / Retrospective
d) CE certificate for the MD (yes, no)
e) Comparator
f) Single-centre only: YES: NO:
g) It is a multicentre investigation with two or more sites in the Czech Republic: YES: NO:
h) It is an international multicentre investigation with one site in the Czech Republic: YES: NO:

1.7 Inclusion criteria:

1.8 Exclusion criteria:

1.9 Approvals:

a) State Institute for Drug Control (SÚKL): YES (date): NO:
b) Other site in the Czech Republic: YES (date, specify): NO:

2 Contact Details

2.1 Principal Investigator:

Full name, academic titles:

Institution, address:

Phone number:

Email:

Co-investigator:

2.2 Sponsor / Funder of the Clinical Investigation:

Name:

Address:

Contact person:

Phone number:

Email:

Company / Tax ID No:

2.3 Applicant / CRO conducting the Clinical Investigation:

Name:

Address:

Contact person:

Phone number:

Email:

Company / Tax ID No:

3 Questions Related to Subjects of the Investigation

3.1 Duration of the clinical investigation for each participant:

3.2 Duration of the clinical investigation for the investigation team:

3.3 Planned number of subjects:

a) At the site:
b) In the Czech Republic:
c) Total:

3.4 Characteristics of the investigation subjects *(tick as appropriate)**:***

Men		Outpatients	
Women		Hospitalised patients	
Healthy volunteers		Patients unable to give informed consent	

3.5 What risks are expected for the investigation subjects *(What ethical issues may arise? If ethical issues arise, how will the investigator address them?)*

3.6 How much time will be given to investigation subjects to consider participation after receiving the subject information sheet?

3.7 What type of informed consent (IC) will be obtained from the subjects or their legal representatives?

	YES	**NO**
Written IC		
Written IC of the subject's legal representatives		
Oral IC (if the subject is unable to write) in the presence of at least one witness In this case, please describe the exact enrolment procedure.		
Cannot be obtained in advance (emergency situations / unconsciousness) In this case, please provide a proposed description of the enrolment procedure.		

3.8 What information will be provided to the subject's attending (GP) physician?

3.9 How will expenses of the investigation subjects be covered?

3.10 Will any other payments be provided to the subjects?

4 Questions Related to Medicinal Products

4.1 List all medications that will be administered as part of the clinical investigation:

4.2 Does the clinical investigation require the application of radioisotopes?
YES (which one): NO:

4.3 Has authorisation for radioisotope application been issued (State Office for Nuclear Safety – SÚJB)?
YES: NO:

4.4 Does the clinical investigation require administration of antimicrobial agents?
YES (which ones): NO:

4.5 If antimicrobial agents are used in the clinical investigation, has the applicant informed the antibiotic centre of the medical facility or the clinical pharmacologist?
YES: NO:

4.6 Does the clinical investigation require any medicines to be discontinued: (If yes, which ones and for how long)*:*

4.7 Is the use of a placebo planned in the control group*:*
YES: NO:

5 Questions Related to Visits and Examinations

5.1 Which of the following examination procedures are included in the clinical investigation:

a) Clinical monitoring only (number)**:**

b) Functional tests (which ones, how many)**:**

c) Blood samples (blood volume, number of venipunctures, blood loss over time)**:**

d) X-ray or radioisotope examination (which ones, how many, radiation dose)**:**

e) CT or MRI examination (which ones, how many)**:**

f) Instrumental invasive methods (which ones, how many)**:**

g) Other examinations (please specify)**:**

h) Tissue samples:

i) Is pharmacokinetics part of the clinical investigation:

j) Does the clinical investigation require DNA testing (if yes, which)**:**

6 Questions Related to Insurance

Liability insurance arranged for the sponsor and the investigator, providing compensation in the event of death of the subject or damage to health resulting from the conduct of the clinical investigation.

6.1 Is insurance arranged for the investigator:

6.2 Is insurance arranged for the sponsor:

6.3 Will the insurance policy contain exclusions from cover (if the relevant part of the insurance policy with exclusions is not attached, please specify which exclusions apply)**:**

6.4 Will the insurance policy include a deductible (if yes, please specify the amount. How will compensation to the subject be ensured if the compensation amount is lower than the deductible agreed in the sponsor's insurance policy)***:***

6.5 Maximum compensation amount agreed in the insurance policy for one investigation subject:

Date

Name and signature of the person completing the questionnaire