Medical Device	Hungary
Competent Authority	
Contact Details	
Contact name 1	National Public Health and Pharmaceutical Center (NNGYK, formerly: OGYÉI)
Contact name 2	Department of Medical Devices
Contact name 3	
Phone	+36 1 886 9300 extension: 329 or 272
Fax	
Email General	
Email Department	amd@nngyk.gov.hu
Address	Zrinyi u. 3/ Mail: 1372 P.O. Box: 450
ZIP/City	1051, Budapest
Country	Hungary
Web address	https://ogyei.gov.hu/orvostechnika/
Additional information	
Clinical Investigation Authorisation / Registration / Notification	
Regulatory & ethics bodies involved in approval proccess	Competent Authority/-ies (CA) Ethics committee(s)
CA - Submission for authorisation mandatory for...	All interventional medical device trials
CE-marked MD used within label are exempted from any notification obligation to CA	Not specified
Guidance on submission of application available	Yes
Guidance on submission of application	https://ogyei.gov.hu/formanyomtatvanyok_orvostechnika
National legal framework in place	Yes
Applicable national legal framework/reference	Decree 235/2009 and Decree 33/2009
Additional information	
Submission Format	
Online portal	
Standard application form available	No
Standard application form	
Standard application form - additional information	
Use of standard application form binding	No
Guidance on submission format available	No

Medical Device	Hungary
Guidance on submission format	
National legal framework in place	Yes
Applicable national legal framework/reference	Decree No 235/2009
Additional information	
Language of Submission	
Language(s) of application	Hungarian
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
National legal framework in place	No
Applicable national legal framework/reference	
Additional information	
Submission Fees	
Fees for trial submission mandatory	Yes
Fees	Application for a clinical trial: 500.000 HUF Application for a non-interventional trial: 370.000 HUF Any substantial modification or amendment that requires a new opinion of Special authorities has the same fee as a new application.
Waiver for academic (non-commercial) studies possible	Not specified
Payment requirements (timelines)	Prior to submission of application
Official guidance on required fees available	Yes
Official guidance on required fees	Fees are provided the homepage of CA:https://ogyei.gov.hu/eljarasi_dijak/ Eljárási díjak (Service Fees) in Hungarian only.
National legal framework in place	No
Applicable national legal framework/reference	
Additional information	All fees payable in advance of the procedure. Fees should be sent or transferred to the account of CA as defined on their homepage.
Timelines Autorisation	
General timespan (maw nr days)	60
Mode of approval	Explicit (written)
Clock-stop possible if complementary information requested	Yes
National legal framework in place	No
Applicable national legal framework/reference	

Medical Device	Hungary
Additional information	
Amendments/Substantial Amendments	
Standard notification form	
Timeline for approval of SA (max nr days)	60
Guidance of submission of SA available	No
Guidance of submission of SA	
National legal framework in place	Yes
Applicable national legal framework/reference	Par 35 of Decree No 235/2009
Additional information	
Safety Reporting	
Sponsor must declare reportable events to	National CA CA(s) of EU&EFTA Member States concerned
Investogator/PI shall separately report any SAE/SADE to CA	Yes
Reportable AEs	Not specified
SUSAR being life-threateningor leading to death must be reported	Not specified
All other SUSARs	Not specified
SAE/SADE must be reported	EU MDR reguirements apply
National standard reporting form available	No
Standard reporting form	The guidance document in EU should be applied: MDCG 2020-10/1 Safety reporting in clinical investigations of medical devices under the Regulation (EU) 2017/745
Reporting format - options	Not specified
Online safety reporting portal	
Provision of annual safety report mandatory	Yes
Annual safety report shall be provided by sponsor to	Not specified
Guidance on AE reporting procedure available	No
Guidance on AE reporting procedure	
National legal framework in place	Yes
Applicable national legal framework/reference	Par 22 of Decree No 33/2009
Additional information	The guidance document in EU should be applied: MDCG 2020-10/1 Safety reporting in clinical investigations of medical devices under the Regulation (EU) 2017/745
End of trial	

Medical Device	Hungary
End of trial declaration: who, when, what?	All clinical investigations requiring authorisation by CA
Responsible for end of trial declaration	Sponsor
Regular termination - declaration of timespan (max nr days)	Not specified
Timespan counted from	Not specified
Early/premature termination - declaration timespan (max nr days)	Not specified
Reasons for early termination shall be clearly declared	Yes
Standard declaration form available	No
Standard declaration form	
Guidance on end of trial declaration available	No
Guidance on end of trial declaration	
National legal framework in place	Yes
Applicable national legal framework/reference	Par 24 of Decree No 33/2009
Additional information	EU MDR regulations apply.
Additional Information & Specifics	
Additional Information & Specifics	
Ethics Committee	
Contact Details	
Contact name 1	Central Ethics Committee/ Public co-authority for MD investigations:
Contact name 2	Scientific Research Ethics Committee of the Medical Research Council - ETT TUKEB
Contact name 3	
Phone	(+36 1) 795-1197 or (+36 1) 795-1198
Fax	
Email General	tukeb@bm.gov.hu
Email Department	tukeb@bm.gov.hu
Address	
ZIP/City	
Country	Hungary
Web address	https://ett.okfo.gov.hu/tukeb/
Additional information	
Ethical Review - General	
Submission for Ethical review mandatory for	All clinical investigations of MD

Medical Device	Hungary
Submission to CA and EC to be performed in the following order	EC first
Procedural interaction between CA and EC during approval proccess	Yes
Procedural interaction - additional information	Ethical review is prior to the submission to CA.
Additional information	The central ethics committees are officially appointed by law as public co-authorities (in the meaning of the general rules of public authority procedures). This is a specific Hungarian phenomenon. The opinion of the co-authority (the ethical approval in the given case) is binding for the decision-making authority (CA).
Single-Centre Studies - Ethical Review	
Ethical approval (favourable opinion) to be obtained from	Central EC (appointed as co-authority) Institutional EC
Additional information	Single-site clinical investigations with medical devices fall in the nationwide competence of TUKEB (acting as co-authority for ethical approval). Institutional ECs do not give approval but they need to be informed about the initiating trial.
Multi-Centre Studies - Ethical Review	
Ethical approval (favourable option) required form	Central EC (appointed as co-authority)
Submission of application required to	Central EC (appointed as co-authority) All local ECs of participating sites
Additional information	Multi-site clinical investigations with medical devices fall in the nationwide competence of TUKEB (acting as co-authority for ethical approval). Institutional ECs do not give approval but they need to be informed about the initiating trial.
Submission of Application	
Responsible for study submission	Sponsor
Entitled to study submission	Sponsor
Prerequisites for submission	Positive opinion by relevant EC(s) Proof of payment of fees Appropriate insurance
Guidance on submission of application available	Yes
Guidance on submission of application	Guidance in Hungarian about submission: https://ogyei.gov.hu/dynamic/iv_kerelem_hatosagi_eljaras_dontes_0505.pdf
National legal framework in place	No
Applicable national legal framework/reference	
Additional information	
Submission Format	
Format option(s)	Electronically
Preferred format	Electronically
Online portal	Preferably using client gate: https://epapir.gov.hu/

Medical Device	Hungary
Standard application form available	No
Standard application form	
Standard application form - additional information	
Use of standard application form binding	No
Guidance on submission format available	No
Guidance on submission format	
National legal framework in place	No
Applicable national legal framework/reference	
Additional information	Submission directly to EC, prior to submission to CA.
Language of Submission	
Language(s) of application	Hungarian
Preferred language of application	Hungarian
English accepted	Partly, not for all documents
Documents mandatory to be in official national language	Basic application form Information material, Documents and Forms intended for study participants and patient information Information on safe use of MD Instructions for use (of CE-marked MD) Labels Agreements concerning the Hungarian arrangement of the investigation
Documents mandatory to be in local language of study site	Not specified
Documents mandatory to be in language of study participant	Not specified
National legal framework in place	No
Applicable national legal framework/reference	
Additional information	
Submission Fees	
Fees for ethical review mandatory	No
Waiver for academic (non-commercial) studies possible	No
Fees for ethical review	There is no fee for TUKEB, when it is issuing an ethical opinion prior to submission to CA (for clinical trials that are planned regarding Article 62 (1) of the MDR).
Official guidance on required fees available	No
Official guidance on required fees	
National legal framework in place	No

Medical Device	Hungary
Applicable national legal framework/reference	Decree No 23/2002
Additional information	
Timelines Ethical Review	
General timespan for single-centre studies (max nr days)	60
General timespan for multi-centre studies (max nr days)	60
Clock-stop possible if complementary information requested	
Timespan counted from	
National legal framework in place	Yes
Applicable national legal framework/reference	Section 3/B of Decree No 235/2009
Additional information	
Amendments/Substantial Amendments	
Ethical review mandatory for	Any substantial amendments
Responsible for submission of SA	Not specified
Standard notification form available	No
Standard notification form	
Timeline for approval of SA (max nr days)	Not specified
Guidance of submission of SA available	No
Guidance on submission of SA	
National legal framework in place	No
Applicable national legal framework/reference	
Additional information	
Safety Reporting	
Reportable AEs	No AE reporting obligation
Investigator shall report SAE to	Competent Authority
Reporting timeline	Not applicable
Responsible for AE reporting to relevant EC(s)	Not applicable
SUSAR being life-threatening or leading to death must be reported	Not applicable
All other SUSAR must be reported	Not applicable
SAE/SADE must be reported	Not applicable
Sponsor is obliged to notify all investigators of SAE/SADE occurence	Yes

Medical Device	Hungary
National standard reporting form available	Not specified
Standard reporting form	
Reporting format - options	
Preferred format	
Online safety reporting portal	
Provision of annual safety report mandatory	Yes
Annual safety report shall be provided by sponsor to	National CA
Guidance on AE reporting procedure available	No
Guidance on AE reporting procedure	
National legal framework in place	No
Applicable national legal framework/reference	
Additional information	Annual Safety report must be provided to EC for clinical investigations on: MD CE-marked use within and outside label, MD without label, respective combination studies with IMPs. The guidance document in EU should be applied: MDCG 2020-10/1 Safety reporting in clinical investigations of medical devices under the Regulation (EU) 2017/745
End of trial	
End of trial declaration mandatory	Yes
Responsible for end of trial declaration	Sponsor
Regular termination - declaration of timespan (max nr days)	Not specified
Timespan counted from	Not specified
Early/premature termination - declaration timespan (max nr days)	Not specified
Reasons for early termination shall be clearly declared	Not specified
Standard declaration form available	No
Standard declaration form	
Guidance on end of trial declaration available	No
Guidance on end of trial declaration	
National legal framework in place	No
Applicable national legal framework/reference	

Medical Device	Hungary
Additional information	End of trial declaration via CA. If the trial cannot be finished until the planned ending date indicated in the study plan, the sponsor should notify the CA.
Additional Information & Specifics	
Additional Information & Specifics	N/A
Study Specific Requirement	
Sponsor	
Sponsor - Definition available in national law	Yes
Sponsor - Definition (pursuant to national law)	„any natural person or legal entity, unincorporated business entity initiating, leading or funding the clinical trial. The investigator and the sponsor may be the same entity“ (pursuant to Section 2(d) of Decree No 235/2005).
Sponsorship mandatory	Yes
Sponsorship mandatory - Additional information	The application for medical research must include a) the name of sponsor, b) its legal representative in Hungary, and c) the address of the legal representative (Decree No 235/2009).
Co-Sponsor - Definition available in national law	No
Co-Sponsor - Definition (pursuant to national law)	
Co-sponsorship allowed	No
Legal representative based in the EU/EEA is mandatory where Sponsor is located outside EU/EEA:	Yes
Additional Information	
Investigator	
Entitled to be principal investigator	Physician
Additional Information	All personnel requirements are specified in Annex 2 ofDecree No 33/2009. There are specific requirements for the personnel of Type I, IIa, IIb and invasive medical device trials. Specific board exam is required for principal investigators.
Study participants - informed consent	
Standard IC form (ICF) available	No
Standard IC form (ICF)	
Standard ICF - Additional Information	
IC is regulated by law	Yes
Informed Consent - Definition/ Requirements	Informed Consent is covered in Art 10, 10/A, 10/B Decree No 33/2009 in detail. Informed Consent is also covered in Act CLIV of 1997 on Health.
Applicable national legal framework/ Reference	Act 10, 10/A, 10/B of Decree No 33/2009 In more general covered in:Act CLIV of 1997 and Decree No 235/2009
Additional Information	

Medical Device	Hungary
Study participants - vulnerable population	
Minors / Children - Studies allowed	Yes Special provisions apply
Specific provision	In clinical trials with minors there should be a patient information sheet adequate for the age group so that the minor is capable of formulating an opinion and assessing the situation. ICF should be signed by the minor and their parents or legal representatives.
Legal framework/Reference (Minors/Children)	Art 10/B Decree No 33/2009 of the Minister of Health Par 13. (5) and Par 159. (4) of Act CLIV of 1997 on Health
Incapacitated persons - Studies allowed	Yes Special provisions apply
Specific provisions	
Legal framework / Reference (Incapacitated persons)	Art 10/B and 15 of Decree No 33/2009 Par. 159. (4) of Act CLIV of 1997 on Health
Emergency situations - Studies allowed	Yes Special provisions apply
Specific provisions	No explicit provisions in national legislation
Emergency situation without prior consent of patient or proxy - Studies allowed	No explicit provisions in national legislation
Conditions allowing trial participation in emergency setting without prior consent	In special urgent cases, when the study is expected to be of direct benefit for the health of the research subject, it may be done without consent.
Legal framework / Reference (Emergency Situation)	
Pregnant or breastfeeding women - Studies allowed	Yes Special provisions apply
Specific provisions	A pregnant or lactating woman can only be the subject of research if it directly benefits the health of herself or her child, or of women and children in a similar stage of life, and there is no procedure available through which similarly effective research can be conducted on a non-pregnant or lactating woman.
Legal framework / Reference (Pregnant or breastfeeding women)	Par. 161(1) of Act CLIV of 1997 on Health
National legal framework for protection of vulnerable populations in place	No
Applicable legal framework / Reference (Vulnerable Population)	
Guidelines & conventions for protection of vulnerable populations	
Additional Information	
Study participants - compensation & reimbursement	
Reimbursement for study participants	Optional Depends on study population (healthy subjects or patients)
Compensation is limited to/provided for	Expenses arising from study participation (e.g. Travel)

Medical Device	Hungary
Additional Information	Compensation for income loss related to participation in the study, as well as costs, particularly in the context of travel or other extra costs are allowed (pursuant to Art 9(10) Decree No 33/2009). Accordingly, travel/food reimbursement are acceptable as compensation for subjects (patients or healthy volunteers) participating in a clinical research.
Study participants - recriutment & trial outcome >> end of study	
Mandatory to inform participant of clinical trial outcome	No
Additional information	
Data protection	
Notification to DP Authority/ Ombudsmann is mandatory	No
Approval/authorisation required	No
Specific notification timelines before operations start	Not applicable
Laguage of notification	Not applicable
Notification format	Not applicable
Notification fee required	N/A
Fee	N/A
Guidance on notification requirements available	No
Guidance on notification requirements	
Data protection authority/agency - contact details	Hungarian National Authority for Data Protection and Freedom of Information / Nemzeti Adatvédelmi és Információszabadság Hatóság
Contact name 2	N/A
Contact name 3	N/A
Phone	+36 -1-391-1400
Fax	36-1-391-1410
E-mail	privacy@naih.hu
Web address	http://www.naih.hu/
Address	Szilágyi Erzsébet fasor 22/C.
ZIP/City	1125, Budapest
Country	Hungary
Additional information	National Data Protection Act: Act XLVII of 1997 on the management and protection of health and related personal data Act CXII of 2011 on the Right of Informational Self-Determination and on Freedom of Information
Archiving & data management	
Study documents must be kept at least (in years)	10

Medical Device	Hungary
National legal framework in place	N/A
Applicable national legal framework/reference	N/A
Additional information	The Clinical study documentation is a part of the Technical documentation of the medical device. Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with Article 56, available for the competent authorities for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market.
National Legislations	
General Information	
Official website providing relevant national legislation available	No
Official website providing relevant national legislation	
Official governmental legal database available	Yes
Official governmental legal database	"Nemzeti Jogszabálytár": the official public source of national legislation (according to the Hungarian Act CXXX. of 2010). Acts and Decrees are available only in Hungarian.
Additional information	
Investigations on Medical Devices	
Applicable national regulations	General Act(s) on Medical/Clinical Research in Humans National Act on Medical Devices
Act on Medical Devices (or comparable national legal framework)	Decree No 33/2009 on clinical investigations with medical devices.
Transposition of Directive 90/385/EEC	Decree No 4/2009 on Medical Devices
Transposition of Directive 93/42/EEC	Decree No 4/2009 on Medical Devices
Transposition of Directive 98/79/EC	Decree No 8/2003 on in-vitro diagnostic medical devices.
Transposition of Directive 2007/47/EC	Decree No 8/2003 on in-vitro diagnostic medical devices.
Other applicable regulations / implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)	• Decree No 235/2009 on rules governing authorisation procedures of biomedical research, clinical trials with investigational medicinal products for human use as well as clinical investigations on medical devices intended for human use. Combination Studies: • Decree No 35/2005 of the Minister of Health on the clinical trial of investigational medicinal products for human use and on the application of the good clinical practice. Non-interventional clinical investigations with medical devices: • Art. 20/A-20/S of Decree 23/2002 on biomedical research on human individuals
Additional Information	
Combination studies (IMP/MD)	

Medical Device	Hungary
Applicable national regulations	Not specified
Legal act applicable to both study types	
Other applicable regulations/implementing provisions (acts, laws, decrees, ordinances, circulars, etc)	
Additional information	Combination studies are briefly mentioned in (10) of MDR Regulation.
Radiation & Radiotherapy	
Specific framework available	Yes
Applicable legal framework	Decree No 2/2002 on the **protection against ionizing radiation** and the **corresponding licensing**, **reporting** and inspection **system**
Additional information	
Biobanking	
Specific framework available	
Applicable legal framework	Act **XXI. of 2008**
Additional information	
Data protection	
Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)	National Data Protection Act
National DP act	Act **XLVII of 1997** on the **management and protection of health and related personal data** ('the Medical Data Act') Act CXII of 2011 on the Right of Informational Self-Determination and on Freedom of Information
Implementing decrees / ordinances	
Other applicable regulations (covering DP related issues)	
Additional Information	
Insurance	
Specific requirements	
Applicable legal framework	As defined in Art. 69 of MDR Regulation.
Additional information	
EC operations/ Fees	
Separate legal framework available	Yes
Applicable legal framework	Medical Research Council/ Ethics Committees: Decree 28/2014. on the Medical Research Council
Additional information	N/A
CA operations/ Fees	
Separate legal framework available	
Applicable legal framework	Decree 235/2009 and Decree 33/2009 are applicable.

Medical Device	Hungary
Additional information	
Additional Information & Specifics	
Additional Information & Specifics	N/A
Definitions	
MD/MD Investigation	
MD - Definition available in national law	No
MD - Definition	Definitions of MD are provided in MDR Regulation.
Investigation of MD - Definition available in national law	Yes
MD Investigation - Definition	
Additional Information	• Clinical investigations on MD: Investigations on CE-marked MD used outside label, non-CE-marked MD, and respective combination studies with IMPs. • Non-Interventional trial on MD: Investigations on CE-marked MD used within label; observational investigations on MD.
Further Definitions	
Additional information	
Additional Information & Specifics	
Additional Information & Specifics Additional Information & Specifics	