Medical Device	Netherlands
Competent Authority	
Contact Details	
Contact name 1	Central Committee on Research Involving Human Subject (CCMO)
Contact name 2	N/A
Contact name 3	N/A
Phone	+31 070 340 6700
Fax	
Email General	devices@ccmo.nl
Email Department	bi@ccmo.nl
Address	Central Committee on Research Involving Human Subjects (CCMO) - PO Box 16302
ZIP/City	2500 BH The Hague
Country	Netherlands
Web address	https://www.ccmo.nl
Additional information	Since 1 October 2020, the Central Committee on Research Involving Human Subjects (Centrale Commissie Mensgebonden Onderzoek, CCMO) has been the (sole) competent authority for all notifications relating to clinical trials with medical devices.
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 research projects involving humans (or any kind of human tissue, cells etc) All classes of MD
CE-marked MD used within label are exempted from any notification obligation to CA	Yes
Guidance on submission of application available	Yes
Guidance on submission of application	
National legal framework in place	Yes
Applicable national legal framework/reference	Dutch Medical Devices Act contains organisational matters that are left to the national governments to regulate: wetten.nl - Regeling - Wet medische hulpmiddelen - BWBR0042755 (overheid.nl)

Medical Device	Netherlands
Additional information	Clinical investigation into the safety and/or (clinical) performance of the medical device falls within the scope of the EU Medical Device Regulation (MDR). Other research in which medical devices are used as part of a study (for example, to measure an endpoint), but in which the safety, performance and/or effectiveness of the medical device itself are not investigated, falls outside the scope of the MDR. These studies may fall under the scope of the Dutch Medical Research Involving Human Subjects Act[Wet Medisch-wetenschappelijk onderzoek met mensen, WMO] or the Dutch Embryo Act [Embryowet].
Submission Format	
Online portal	Pending the availability of Eudamed, investigational applications must be register by completing the ABR form (General Assessment and Registration form) (version May 2021) in ToetsingOnline (available until July 2025, link to the new portal here). Clinical investigations in the context of conformity purposes (MDR article 62/74.2) • For clinical investigations in the context of conformity purposes (MDR article 62/74.2) the research file is first validated by CCMO. • After a positive decision on the validation, CCMO will transfer your file to the review committee (accredited MREC or CCMO) for assessment. • You are required to submit your research file digitally to CCMO, by email at devices@ccmo.nl (don't forget to state the file number (NL number) listed on the ABR form in your email). Other clinical investigations (MDR article 82) or post-market clinical follow-up investigations (MDR article 74.1) • Submit a file directly to the MREC of your choice. Please follow the instructions of the MREC concerned. • Submit your file to tc@ccmo.nl if CCMO serves as review committee.
Standard application form available	Yes
Standard application form	Available on the website ToetsingOnline (until July 2025). New portal after this date.
Standard application form - additional information	When finalising the ABR form you are required to select either an accredited MREC or CCMO to submit your file to. In the case of clinical investigations that fall under article 62 or 74.2 of the MDR, the study must be submitted to CCMO for validation. After a positive validation decision, CCMO forwards your file to the review committee (accredited MREC or CCMO) which you have indicated as your preference in the cover letter. If you have not indicated a preference, CCMO determines which review committee will assess your clinical investigation. CCMO transfers the ABR form in ToetsingOnline to this review committee. In all other cases you may submit the file directly to the review committee that you have selected in the ABR form.
Use of standard application form binding	N/A
Guidance on submission format available	Yes

Medical Device	Netherlands
Guidance on submission format	Related information are available on the CCMO website in section: Home>Investigators>clinical Investigations with medical devices.
National legal framework in place	Yes
Applicable national legal framework/reference	The Dutch Medical Devices Act [Wet medische hulpmiddelen] contains organisational matters that are left to the national governments to regulate.
Additional information	N/A
Language of Submission	
Language(s) of application	Dutch English
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	Yes
Applicable national legal framework/reference	
Additional information	For the primary submission to an accredited MREC or CCMO, the list of documents to be submitted are listed here. More precision: Overview of documents to be submitted for clinical investigations with medical devices
Submission Fees	
Fees for trial submission mandatory	Yes
Fees	In the Netherlands, national fees are set for medical-ethical review of research with a medical device and a medical device for in-vitro diagnostics. For the evaluation of clinical trials on medical devices carried out for compliance purposes, Article 62/74.2 of Regulation (EU) 2017/745 on medical devices (MDR) applies. For other research files falling within the scope of the MDR (MDR article 74.1 or 82), the fee of the review committee concerned applies instead of the national fee. These fees are collected by the relevant ethics committee (accredited MREC).
Waiver for academic (non-commercial) studies possible	Reduced fees are charged
Payment requirements (timelines)	Not specified
Official guidance on required fees available	Yes
Official guidance on required fees	An overview of all the conditions that apply to the fees, can be downloaded via: Terms and conditions fees.
National legal framework in place	Yes
Applicable national legal framework/reference	In the Netherlands, national fees are set for medical-ethical review of research with a medical device and a medical device for in-vitro diagnostics.
Additional information	N/A
Timelines Autorisation	
General timespan (maw nr days)	Max 10 (+5) days. If request for information: response sponsor in max. 10(+20+5) days

Medical Device	Netherlands
Mode of approval	Tacit (Silent)
Clock-stop possible if complementary information requested	Yes
National legal framework in place	N/A
Applicable national legal framework/reference	N/A
Additional information	Validation of clinical investigations for conformity purposes (MDR article 62/74.2) is carried out by CCMO. CCMO checks whether the clinical investigation falls within the scope of the MDR and whether the research file is complete. The check for completeness only concerns the presence of all documents; it is not a substantive assessment. If the clinical investigation falls within the scope of the MDR and the research file is complete, CCMO sends the file to the review committee of your choice, after which the assessment of the investigation begins. See the procedure and the deadline in the figurehere.
Amendments/Substantial Amendments	
Standard notification form	Modifications of the research file during the investigation should be reported to the review committee (accredited MREC or CCMO). **No need to report modifications to CCMO as competent authority.**
Timeline for approval of SA (max nr days)	Not applicable
Guidance of submission of SA available	N/A
Guidance of submission of SA	N/A
National legal framework in place	N/A
Applicable national legal framework/reference	
Additional information	
Safety Reporting	
Sponsor must declare reportable events to	Reviewing committee (CCMO or MREC)
Investogator/PI shall separately report any SAE/SADE to CA	No
Reportable AEs	Not applicable
SUSAR being life-threateningor leading to death must be reported	Not applicable
All other SUSARs	N/A
SAE/SADE must be reported	N/A
National standard reporting form available	Not applicable
Standard reporting form	
Reporting format - options	Not applicable
Online safety reporting portal	
Provision of annual safety report mandatory	No
Annual safety report shall be provided by sponsor to	Relevant EC(s)

Medical Device	Netherlands
Guidance on AE reporting procedure available	Yes
Guidance on AE reporting procedure	
National legal framework in place	Yes
Applicable national legal framework/reference	
Additional information	
End of trial	
End of trial declaration: who, when, what?	All clinical trials requiring authorisation by CA
Responsible for end of trial declaration	Sponsor Manufacturer acting as sponsor
Regular termination - declaration of timespan (max nr days)	15 15d for Clinical investigations for conformity purposes (MDR article 62/74.2) or post-market clinical follow-up investigations
Timespan counted from	As defined in the investigation protocol
Early/premature termination - declaration timespan (max nr days)	For safety reasons: within 24 hours. Reasons other than safety; 15 calendar days
Reasons for early termination shall be clearly declared	Yes
Standard declaration form available	No
Standard declaration form	
Guidance on end of trial declaration available	Yes
Guidance on end of trial declaration	More information available here
National legal framework in place	Yes
Applicable national legal framework/reference	Art 13(5) Medical Devices Decree (Dutch)
Additional information	N/A
Additional Information & Specifics	
Additional Information & Specifics	
Ethics Committee	
Contact Details	
Contact name 1	Medical Research Ethics Committees MRECs or Central Committee on Research Involving Human Subjects (CCMO)
Contact name 2	N/A
Contact name 3	N/A
Phone	+31 070 340 6700
Fax	N/A
Email General	devices@ccmo.nl
Email Department	N/A
Address	N/A
ZIP/City	N/A

Medical Device	Netherlands
Country	N/A
Web address	https://english.ccmo.nl/investigators/clinical-investigations-with-medical-devices
Additional information	**Primary submission investigations with clinical devices** To select an authorised MREC you may use the online tool Committee Finder.
Ethical Review - General	
Submission for Ethical review mandatory for	All research projects involving humans (or any kind of human tissue, cells etc)
Submission to CA and EC to be performed in the following order	CA first
Procedural interaction between CA and EC during approval proccess	Yes
Procedural interaction - additional information	The EU Medical Device Regulation (MDR) stipulates that clinical investigations for conformity purposes (MDR article 62/74.2) must be validated before they can be assessed by a review committee. In Netherlands, validation of clinical investigations for conformity purposes is carried out by CCMO. CCMO checks whether the clinical investigation falls within the scope of the MDR and whether the research file is complete. After a positive decision on the validation, CCMO will transfer your file to the review committee (accredited MREC or CCMO) for assessment.
Additional information	CCMO will transfer your file to the review committee of your preference. If you did not indicate a preference for a review committee, CCMO will assign your file to a review committee.
Single-Centre Studies - Ethical Review	
Ethical approval (favourable opinion) to be obtained from	An authorised review committee accredited: Medical Research Ethics Committee (MREC) or CCMO
Additional information	To select an authorised MREC you may use the online tool Committee Finder. A limited number of review committees are authorised for clinical investigation with high-risk medical devices in the context of conformity purposes (see table here).
Multi-Centre Studies - Ethical Review	
Ethical approval (favourable option) required form	Central EC (authorised to issue a single opinion)
Submission of application required to	Only one accredited Medical Research Ethics Committee (MREC) or CCMO
Additional information	
Submission of Application	
Responsible for study submission	Sponsor Manufacturer acting as sponsor
Entitled to study submission	Not applicable
Prerequisites for submission	Not specified
Guidance on submission of application available	Yes

Medical Device	Netherlands
Guidance on submission of application	The procedure and the content of the submission of a research file is provided on the CCMO website in section: Home>Investigators>Clinical investigations with medical devices >Primary submission investigations with clinical devices>How to submit
National legal framework in place	Yes
Applicable national legal framework/reference	Art 13(3) Medical Devices Decree (Dutch)
Additional information	N/A
Submission Format	
Format option(s)	Online portal Electronically
Preferred format	Online portal Electronically
Online portal	You are required to register your clinical investigation with a medical device before submitting your research file to the review committee. Pending the availability of Eudamed, investigational applications must be register by completing the ABR form (General Assessment and Registration form) (version May 2021) in ToetsingOnline.
Standard application form available	Yes
Standard application form	ABR form (General Assessment and Registration form) (version May 2021) in ToetsingOnline (until July 2025)
Standard application form - additional information	When finalising the ABR form you are required to select either an accredited MREC or CCMO to submit your file to. In the case of clinical investigations that fall under article 62 or 74.2 of the MDR, the study must be submitted to CCMO for validation. After a positive validation decision, CCMO forwards your file to the review committee (accredited MREC or CCMO) which you have indicated as your preference in the cover letter. If you have not indicated a preference, CCMO determines which review committee will assess your clinical investigation. CCMO transfers the ABR form in ToetsingOnline to this review committee. In all other cases you may submit the file directly to the review committee that you have selected in the ABR form.
Use of standard application form binding	Yes
Guidance on submission format available	N/A
Guidance on submission format	Related information are available on theCCMO website in section: Home>Investigators>clinical Investigations with medical devices.
National legal framework in place	Yes
Applicable national legal framework/reference	N/A
Additional information	
Language of Submission	
Language(s) of application	Dutch English
Preferred language of application	N/A

Medical Device	Netherlands
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	N/A
Documents mandatory to be in language of study participant	N/A
National legal framework in place	Yes
Applicable national legal framework/reference	N/A
Additional information	For the primary submission to an accredited MREC or CCMO, the list of documents to be submitted are listedhere. More precision: Overview of documents to be submitted for clinical investigations with medical devices
Submission Fees	
Fees for ethical review mandatory	Yes
Waiver for academic (non-commercial) studies possible	Reduced fees are charged
Fees for ethical review	In the Netherlands, national fees are set for medical-ethical review of research with a medical device and a medical device for in-vitro diagnostics. For the evaluation of clinical trials on medical devices carried out for compliance purposes, Article 62/74.2 of Regulation (EU) 2017/745 on medical devices (MDR) applies. For other research files falling within the scope of the MDR (MDR article 74.1 or 82), the fee of the review committee concerned applies instead of the national fee. These fees are collected by the relevant ethics committee (accredited MREC).
Official guidance on required fees available	Yes
Official guidance on required fees	An overview of all the conditions that apply to the fees, can be downloaded via: Terms and conditions fees.
National legal framework in place	Yes
Applicable national legal framework/reference	In the Netherlands, national fees are set for medical-ethical review of research with a medical device and a medical device for in-vitro diagnostics.
Additional information	N/A
Timelines Ethical Review	
General timespan for single-centre studies (max nr days)	Max 45d (+20 in case of experts consultation) for Class IIa Invasive, Class IIb Invasive, class III
General timespan for multi-centre studies (max nr days)	Max 45d (+20 in case of experts consultation) for Class IIa Invasive, Class IIb Invasive, class III
Clock-stop possible if complementary information requested	Yes
Timespan counted from	Date of receipt of valid and complete application
National legal framework in place	N/A
Applicable national legal framework/reference	N/A

Medical Device	Netherlands
Additional information	Related information is provided on the CCMO website in section Home>Investigators>Primary submission to the reviewing committee>**Validation by CCMO of clinical investigations for conformity purposes** Different deadlines are used for the assessment of clinical investigations with medical devices for the primary submission and for amendments depending on the medical device class. Please click here to find out which time limit applies to your investigation.
Amendments/Substantial Amendments	
Ethical review mandatory for	Any substantial amendments
Responsible for submission of SA	Sponsor Manufacturer acting as sponsor
Standard notification form available	Yes
Standard notification form	According to the amendment, f the content of information in the ABR form (B1) changes, you need to make and submit a new version of the ABR form. It is not required to modify the blocked questions at C17a for studies with a positive decision before May 26, 2021.
Timeline for approval of SA (max nr days)	MDR 62/74.1/74.2: for all medical device classes: Up to 38 (+ 7 if expert opinion) calendar days + clock stop
Guidance of submission of SA available	Yes
Guidance on submission of SA	More information here.
National legal framework in place	N/A
Applicable national legal framework/reference	N/A
Additional information	Documents which need to be submitted are listedhere. A signed cover letter (A1) with a description of the amendment(s) and an overview of all documents submitted is required. It is up to the review committee to determine whether a further assessment is required.
Safety Reporting	
Reportable AEs	SAE (Serious Adverse Event) Device deficiency, potentially leading to SAE
Investigator shall report SAE to	Sponsor
Reporting timeline	Immediately, not later than 2d (SAE indicating an imminent risk of death, serious injury, or serious illness) Report to sponsor without undue delay but not later than 3 calendar days (SAE (Serious Adverse Event) / Device Deficiency)
Responsible for AE reporting to relevant EC(s)	Sponsor Manufacturer acting as sponsor
SUSAR being life-threatening or leading to death must be reported	N/A
All other SUSAR must be reported	N/A
SAE/SADE must be reported	Within a max of 3d upon first knowledge

Medical Device	Netherlands
Sponsor is obliged to notify all investigators of SAE/SADE occurence	N/A
National standard reporting form available	Other (see info in 'Standard Reporting Form')
Standard reporting form	MDCG 2020-10/2 safety report form
Reporting format - options	Online portal
Preferred format	Online portal
Online safety reporting portal	ToetsingOnline
Provision of annual safety report mandatory	Yes
Annual safety report shall be provided by sponsor to	MREC or CCMO which assessed the investigation
Guidance on AE reporting procedure available	Yes
Guidance on AE reporting procedure	The procedures for safety reports are described in MDCG guidance 2020-10/1
National legal framework in place	Yes
Applicable national legal framework/reference	A calamity must be reported to Dutch Health and Youth Inspectorate (IGJ) within 3 working days (https://www.igj.nl/onderwerpen/calamiteiten/melding-doen-van-een-calamiteit)
Additional information	Because Eudamed is not available as yet, the sponsor is required to upload the safety information through ToetsingOnline. The review committee will receive a message that the safety information (SAE, line listing) has been uploaded and can start the assessment. Safety reports of studies with a positive decision prior to 26 May 2021 and not subject to the Dutch Medical Research Involving Human Subjects Act [Wet medisch-wetenschappelijk onderzoek met mensen, WMO] may be reported at devices@ccmo.nl. These should also be reported to the review committee.
End of trial	
End of trial declaration mandatory	Yes
Responsible for end of trial declaration	Sponsor Manufacturer acting as sponsor
Regular termination - declaration of timespan (max nr days)	15 15d for Clinical investigations for conformity purposes (MDR article 62/74.2) or post-market clinical follow-up investigations
Timespan counted from	N/A
Early/premature termination - declaration timespan (max nr days)	For safety reasons: within 24 hours. Reasons other than safety; 15 calendar days
Reasons for early termination shall be clearly declared	Yes
Standard declaration form available	Yes
Standard declaration form	Form for for Early termination Form for End of study in accordance with the investigation protocol
Guidance on end of trial declaration available	Yes
Guidance on end of trial declaration	More information available here

Medical Device	Netherlands
National legal framework in place	Yes
Applicable national legal framework/reference	Art 13(5) Medical Devices Decree (Dutch)
Additional information	N/A
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)	"the person conducting the scientific research: a person, company, institution organisation that assumes responsibility for the start-up, management and or the funding of scientific research"
Sponsorship mandatory	Yes
Sponsorship mandatory - Additional information	N/A
Co-Sponsor - Definition available in national law	No
Co-Sponsor - Definition (pursuant to national law)	N/A
Co-sponsorship allowed	N/A
Legal representative based in the EU/EEA is mandatory where Sponsor is located outside EU/EEA:	Yes
Additional Information	N/A
Investigator	
Entitled to be principal investigator	Physician Persons who are experts in the field of scientific research and of which at least one is an expert in the field
Additional Information	N/A
Study participants - informed consent	
Standard IC form (ICF) available	Yes
Standard IC form (ICF)	Templates for the Dutch informed consent form, the Dutch Patient Information Form (PIF) and for other information material for research subjects are provided on the CCMO website in section Home>Investigators>Standard research file>E. Information for the research subjects.
Standard ICF - Additional Information	The templates are updated regularly. At all times, use de most recent versions of the templates as available on following website.
IC is regulated by law	Yes
Informed Consent - Definition/ Requirements	“informed, written, dated and signed consent to take part in a clinical trial” (pursuant to Section 1(1.u) WMO (en)). There are special provisions regarding informed consent including consent obtained in vulnerable populations are specified in section 6 of WMO (en)

Medical Device	Netherlands
Applicable national legal framework/ Reference	Section 1(1.u) WMO (en): Definition Section 6 of WMO (en): Provisions, vulnerable populations
Additional Information	"the person carrying out the scientific research means a doctor or a person referred to in Article 3(f) who is responsible for carrying out the scientific research research at a particular location. If the actual implementation is carried out by an employee or other auxiliary person, the person who uses that person shall be as the person conducting the investigation"
Study participants - vulnerable population	
Minors / Children - Studies allowed	With limitations
Specific provision	Clinical trials including minors are possible under special provisions according to the section 4, 6 and 13(e) of WMO (en). The WMO applies the “no, unless” principle. Related information and specific documents (“Non-therapeutic research on minors and incapacitated subjects: 'no, unless” and “Code of conduct involving minors”) are provided on the CCMO website in section: Home>Investigators>Additional information on certain types of research>Research with subjects under the age of 16 years (children) or Research with incapacitated subjects.
Legal framework/Reference (Minors/Children)	Section 4 and 6 of WMO (en)
Incapacitated persons - Studies allowed	Special provisions apply
Specific provisions	
Legal framework / Reference (Incapacitated persons)	Section 4 and 6 of WMO (en)
Emergency situations - Studies allowed	Special provisions apply
Specific provisions	Clinical investigations on MD in emergency situations are possible under special provisions.
Emergency situation without prior consent of patient or proxy - Studies allowed	With limitations
Conditions allowing trial participation in emergency setting without prior consent	"If the clinical trial can be conducted only in medical emergencies in which the consent required pursuant to subsection 1 cannot be given and if inclusion in the trial may benefit the person in urgent need of medical treatment, procedures to implement the trial may be undertaken without such consent for as long as circumstances continue to prevent the giving of consent.“
Legal framework / Reference (Emergency Situation)	Section 6(4) WMO (en)
Pregnant or breastfeeding women - Studies allowed	Special provisions apply
Specific provisions	Specific rules exist for research on fetuses, pregnant and/or breastfeeding women
Legal framework / Reference (Pregnant or breastfeeding women)	
National legal framework for protection of vulnerable populations in place	N/A

Medical Device	Netherlands
Applicable legal framework / Reference (Vulnerable Population)	N/A
Guidelines & conventions for protection of vulnerable populations	N/A
Additional Information	N/A
Study participants - compensation & reimbursement	
Reimbursement for study participants	Optional
Compensation is limited to/provided for	Inconvenience, Pain, Discomfort Expenses arising from study participation (e.g. Travel)
Additional Information	There are no detailed instructions regarding the amount of compensation for research subjects for participating in a clinical trial. The most important elements for the review of a proposed financial compensation for the research subjects are: • any expenses made are always reimbursed; • financial compensation is based on invested time, on the basis of the minimum wage and the burden of the research; • a higher financial compensation is not ruled out, as long as there is sufficient reason for doing so; • the compensation is not based on the risks; • the type of research (therapeutic or non-therapeutic) and the phase of research can be used for determing the amount of the financial compensation deemed acceptable for/appointed to the patients.
Study participants - recriutment & trial outcome >> end of study	
Mandatory to inform participant of clinical trial outcome	Yes
Additional information	The investigator will inform the study participant about the most important results of the study, and about the treatment /group the study participant was in. If the participant prefers not to know, he has to tell the investigator who won't inform him.
Data protection	
Notification to DP Authority/ Ombudsmann is mandatory	No
Approval/authorisation required	No
Specific notification timelines before operations start	N/A
Laguage of notification	N/A
Notification format	N/A
Notification fee required	N/A
Fee	N/A
Guidance on notification requirements available	N/A
Guidance on notification requirements	N/A
Data protection authority/agency - contact details	Dutch Data Protection Authority DPA (College Bescherming Persoonsgegevens, CBP)
Contact name 2	N/A

Medical Device	Netherlands
Contact name 3	N/A
Phone	(+31) - (0)70 - 888 85 00
Fax	(+31) - (0)70 - 888 85 01
E-mail	N/A
Web address	https://www.autoriteitpersoonsgegevens.nl/en
Address	PO Box 93374
ZIP/City	2509 AJ The Hague
Country	Netherlands
Additional information	The DPA is the supervisory body and monitors the compliance with the laws governing the use of personal data. The Dutch Personal Data Protection Act lays down the main rules for handling and protecting personal data. It has been translated into a code of conduct known as the Use of Data in Health Research (Code Goed Gedrag) NB! There is a new law that enables the Dutch government to give (very, very high) penalties (in euros) if you break the law on this point.
Archiving & data management	
Study documents must be kept at least (in years)	10 15
National legal framework in place	N/A
Applicable national legal framework/reference	N/A
Additional information	A **minimum retention period of 10 years** is required for the documentation of research with medical devices after the end of the study with the device. When the medical device is put on the market, the minimum retention period of 10 years starts when the last device has been put on the market. A **minimum retention period of 15 years** is required for research with an implantable medical device. These retention periods have been laid down in Annex XV Chapter III section 3 of the EU Medical Device Regulation 2017/745 (MDR). Information available here.
National Legislations	
General Information	
Official website providing relevant national legislation available	Yes
Official website providing relevant national legislation	wetten.overheid.nl
Official governmental legal database available	N/A
Official governmental legal database	N/A
Additional information	N/A
Investigations on Medical Devices	
Applicable national regulations	General Act(s) on Medical/Clinical Research in Humans National Act on Medicinal Products and Medical Devices EU Medical Devices Regulation (EU no 2017/745, MDR)

Medical Device	Netherlands
Act on Medical Devices (or comparable national legal framework)	Dutch Medical Research Involving Human Subjects Act Dutch Medical Devices Act
Transposition of Directive 90/385/EEC	N/A
Transposition of Directive 93/42/EEC	N/A
Transposition of Directive 98/79/EC	N/A
Transposition of Directive 2007/47/EC	N/A
Other applicable regulations / implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)	In the case of clinical investigations with medical devices, first of all it must be determined whether the study falls within the scope of the EU Medical Device Regulation (MDR) and if so, which legal frame applies. Which legislation and transitional arrangements apply? Information on relevant topics related to the MDR can be found here.
Additional Information	N/A
Combination studies (IMP/MD)	
Applicable national regulations	Depending on whether considered as MP or MD
Legal act applicable to both study types	N/A
Other applicable regulations/implementing provisions (acts, laws, decrees, ordinances, circulars, etc)	Research in which medical devices are used as part of a study (for example, to measure an endpoint), but in which the safety, performance and/or effectiveness of the medical device itself are not investigated, falls outside the scope of the MDR. These studies may fall under the scope of the Dutch Medical Research Involving Human Subjects Act [Wet Medisch-wetenschappelijk onderzoek met mensen, WMO] or the Dutch Embryo Act [Embryowet].
Additional information	N/A
Radiation & Radiotherapy	
Specific framework available	No
Applicable legal framework	N/A
Additional information	During some types of medical scientific research, subjects are exposed to ionizing radiation. Since this can lead to certain health risks for the subjects, it is important to make a comparative assessment of these risks and the potential benefits of the research. In order to develop univocal guidelines regarding this subject, a subcommittee of the Netherlands Commission on Radiation Dosimetry (NCS) summarized the existing literature about the risks of radiation exposure for patients and healthy volunteers participating in clinical research. The conclusions of this literature study and the resulting recommendations are described in the report Human exposure to ionizing radiation for clinical and research purposes which was published in May 2016. Investigators and MRECs can use this report to make a comparative assessment of the risks of ionizing radiation for subjects and the possible benefits of the research for the individual patient, a group of patients, society and/or science.
Biobanking	
Specific framework available	N/A
Applicable legal framework	N/A

Medical Device	Netherlands
Additional information	N/A
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	Dutch Personal Data Protection Act (unofficial English translation) / Wet Bescherming Persoonsgegevens WBP: WBP lays down the main rules for handling and protecting personal data
Implementing decrees / ordinances	N/A
Other applicable regulations (covering DP related issues)	WBP has been translated into a code of conduct known as the Use of Data in Health Research(Code Goed Gedrag).
Additional Information	N/A
Insurance	
Specific requirements	Yes
Applicable legal framework	Insurance Decree (Verzekeringsbesluit) - 1th of July 2015 & Section 7 WMO (en)
Additional information	People participating in research covered by the Medical Research Involving Human Subjects Act (WMO) must be insured against any potential damages incurred as a result of participating in the research. The insurance must comply with specific regulations stated in the Compulsory Insurance Decree in Medical Research Involving Human Subjects (dd 1-7-2015). Exemption from this insurance obligation is possible under certain conditions. In this case, a request must be included in the submitted application. Even if exemption from the WMO insurance obligation is granted, the liability insurance must still be covered. If the research is carried out by an ministerial appointed institution, service or governmental organization, such as those which fall under the Ministry of Health, Welfare and Sport, or the Ministry of Defence, then a WMO human subject insurance or a liability insurance is not needed (section 7, sub 10 WMO).
EC operations/ Fees	
Separate legal framework available	N/A
Applicable legal framework	N/A
Additional information	N/A
CA operations/ Fees	
Separate legal framework available	N/A
Applicable legal framework	N/A
Additional information	N/A
Additional Information & Specifics	
Additional Information & Specifics	N/A
Definitions	

Medical Device	Netherlands
MD/MD Investigation	
MD - Definition available in national law	Yes
MD - Definition	see Art 1 Medical Device Act (Dutch)
Investigation of MD - Definition available in national law	N/A
MD Investigation - Definition	N/A
Additional Information	Combination studies: The question of whether a research with a medical device or active implant falls under the scope of the regulations for research with a medicinal product as laid down in the WMO, is important when the medical device (or active implant) also contains a medicinal product. The CCMO (Central Committee on Research Involving Human Subjects) does not consider medical devices combined with medicinal products as a medicinal product as long as the effect of the medicinal product has a subordinate function with regards to the function of the medical device. A drug eluting stent is an example of this. The legislation for research with medicinal products is not applicable in this case.
Further Definitions	
Additional information	N/A
Additional Information & Specifics	
Additional Information & Specifics Additional Information & Specifics	N/A