# Medical Devices - NETHERLANDS

## Competent authority

<table>
<thead>
<tr>
<th>Contact Details</th>
<th>Contact Name 1</th>
</tr>
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<tbody>
<tr>
<td>Health Care Inspectorate IGZ (Inspectie voor de Gezondheidszorg)</td>
<td></td>
</tr>
</tbody>
</table>

### Phone
+31 088 - 1205000

### Fax
+31 088-120 50 01

### Email Department
meldpunt@igz.nl

### Address
PO Box 2680

### ZIP/City
3500 GR Utrecht

### Country
Netherlands (NL)

### Web address
http://www.igz.nl

### Additional Information
No local CA!
meldpunt@igz.nl (IGZ Information Desk- Submission of Notification)

## Trial Authorisation / Registration / Notification

### Regulatory and ethics bodies involved in approval process
Competent Authority/-ies (CA)
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

#### National trial registry - Registration mandatory
Yes

# The Nederlands Trial Register (NTR)
**Additional Information**

Since the EC already approved the investigation, the IGZ will only perform a minor assessment.

**Submission to CA and EC to be performed in the following order**

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**Submission of Application**

**Responsible for study submission**

Sponsor
Manufacturer acting as sponsor

**Entitled to study submission**

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**Prerequisites for submission**

Positive opinion by relevant EC(s)
Appropriate insurance

**Applicable national legal framework/ Reference**

Art 13 Medical Devices Decree (Dutch)
Art 7 of the Dutch decree on active implants

**Submission Format**

**Format option(s)**

 Electronically

**Preferred format**

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**Standard application form**

Notification form Clinical Investigation with Medical Device (IMD)

**Guidance on submission format**

Related information and notification form is available on IGZ website in section: Home>English>Medical devices>Clinical research involving the use of medical devices or on the CCMO website in section: Home>Investigators>Types of research>Research with a medical device

**Language of Submission**

**Language(s) of application**

English

**Preferred language of application**

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**English accepted**

Partly (Clinical trial applications may be written in English)

**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**

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**Documents mandatory to be in language of the study participant**

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**Submission Fees**

**Fees for trial submission mandatory**

No
Fees
IGZ review is free of charge.

Timelines Authorisation

**General timespan (max nr days)**
14

**Mode of approval (General)**
Explicit

**Timespan counted from**
—

**Additional Information**
When the IGZ has all requested information and there are no additional questions, the IGZ will send a formal (written) acknowledgement that the obligation of notification under the decree has been fulfilled. The manufacturer is requested to send a copy of this letter of confirmation to the principal investigator and to inform the IGZ when foreign healthcare inspectorates, like the Food and Drug Administration (FDA), want to inspect files of Dutch patients participating in the investigation.

Related information is available on IGZ website in section: Home>English>Medical devices>Clinical research involving the use of medical devices

Amendments/Substantial Amendments (SA)

**Notification mandatory for**
—

**Authorisation mandatory for**
All clinical trials requiring notification to CA (without approval process)
All clinical investigations requiring authorisation by CA

**Responsible for submission of SA**
Sponsor

**Standard notification form available**
Yes

**Standard notification form**
Submission online via DIMDI platform

**Timeline for approval of SA (max nr days)**
30

**Applicable national legal framework/ Reference**
§ 22c MPG

**Additional Information**
Implicit approval of substantial amendments.

Safety Reporting

**Responsible for AE reporting to CA**
Sponsor
Manufacturer acting as sponsor

**Sponsor must declare reportable events to**
Competent Authority
CA(s) of EU&EFTA Member States concerned
All participating sites
Reportable AEs

SAE (Serious Adverse Event)

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

All other SUSARs

SAE /SADE must be reported

Immediately (without delay)

National standard reporting form available

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

Standard Reporting Form

Reporting procedure and format: According to the European SAE reporting guidelines MEDDEV 2.7/3 (2010) including MEDDEV 2.7/3 Reporting form.

Reporting format - Options

Preferred format

Annual safety report shall be provided by sponsor to

Guidance on AE reporting procedure

Related information is available on IGZ website in section: Home>English>Medical devices>Clinical research involving the use of medical devices or on CCMO website in section: Home>Investigators>Types of research>Research with a medical device

Additional Information

MDs with CE-mark, used within label: SAEs occurring in a clinical investigation with CE mark must be reported by the manufacturer to the Health Care Inspectorate conform the Europena Guidelines on a MD vigilance system MEDDEV 2.12.1.

Reporting timelines: within 2 working days, and no longer that 4 calendar days about SAEs which have happened during the clinical trial in the participating centers (both in the Netherlands and other member states)

Investigator shall report SAE to

Reporting timeline

End of trial declaration mandatory for

All clinical trials requiring authorisation by CA

Responsible for End of trial declaration

Sponsor
Manufacturer acting as sponsor

Regular Termination - Declaration timespan (max nr days)

90
Timespan counted from

Early/premature Termination - Declaration timespan (max nr days)
Within two working days and no later than four calendar days

Reasons for early termination shall be clearly stated
Yes

Guidance on End of trial declaration
Related information is available on IGZ website in section: Home>English>Medical devices>Clinical research involving the use of medical devices or on CCMO website in section: Home>Investigators>Types of research>Research with a medical device

Applicable national legal framework/ Reference
Art 13(5) Medical Devices Decree (Dutch)

Additional Information & Specifics

Additional Information
Medical devices>Clinical research involving the use of medical devices
• National Portal: ToetsingOnline is an internet portal for the submission, review, registration and publication of medical research involving human subjects. The portal is only used for clinical research which falls under the scope of the WMO (en)

Ethics committee

Contact Details

Contact Name 1
Medical Research Ethics Committees MRECs/METCs

Web address

Additional Information
24 accredited MRECs / METCs.
Links to the MRECs and their contact data are provided on the CCMO website.

Ethical Review - General

Submission for Ethical review mandatory for
Clinical research with MD

Submission to CA and EC to be performed in the following order
EC first

Additional Information
Both the accredited MRECs/METCs and the IGZ are independent governmental bodies with a legal status that reach a legally binding decision on research protocols, and thus are not advisory boards.

Regulatory and ethics bodies involved in approval process

Single-Centre Studies - Ethical Review

Ethical approval (favourable opinion) to be obtained from
An accredited Medical Research Ethics Committee (MREC)
### Multi-Centre Studies - Ethical Review

**Ethical approval (favourable opinion) required from**

Only one accredited Medical Research Ethics Committee (MREC/METC)

**Submission of application required to**

- 

**Additional Information**

The majority of the MRECs/METCs review multicentre research for all of the institutions in the Netherlands.

The approval ("research declaration") of the board of directors from each of the participating sites is required for execution of the study in its own institution.

Ethical Review procedure for multi-centre trials is specified on the CCMO website in section: Home>Investigators>Review procedure>Multicenter research

### Submission of Application

**Responsible for study submission**

- 

**Entitled to study submission**

- 

**Prerequisites for submission / approval**

- 

**Guidance on study submission**

The procedure and the content of the submission of a research file is provided on the CCMO website in section: Home>Investigators>Types of research>Research with a medical device or Home>Investigators >Standard Research file

**Applicable national legal framework/ Reference**

Art 13(3) Medical Devices Decree (Dutch)

### Submission Format

**Format option(s)**

- Paper hardcopy
- Electronically

**Preferred format**

may differ between the competent ECs

**Additional Information**

The required format depends on concerned reviewing committee.

### Language of Submission

**Language(s) of application**

- Dutch
- English

**Preferred language of application**

- 

**Additional Information**

In general, the accredited MREC/ METC of the region where the chief investigator is located is designated the reviewing committee. But sponsors can in principle choose any accredited MREC/METC that meets the requirements.

The approval of the board of directors of the participating center at which the MREC/METC is located is required.
**English accepted**
Partly (Clinical Trial Application may be written in English)

**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

**Fees for Ethical review**
MRECs/ METCs charge varying reviewing fees for commercial and investigator driven/academic trials. There is no national agreement on the costs.

Further information on respective fees of the accredited MRECs/METCs can be found on the CCMO websites in section: Home>MRECs>Accredited MRECs

### Timelines Ethical Review

**General timespan for single-centre studies (max nr days)**
Max. 8 weeks (extension of a max duration of 8 weeks is possible in some cases).

**General timespan for multi-centre studies (max nr days)**
Max. 8 weeks (extension of a max duration of 8 weeks is possible in some cases).

**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

**Additional Information**
Reviewing timelines apply to ‘general’ medical research (non- MP research).

Related information is provided on the CCMO website in section Home>Investigators>Primary submission to the reviewing committee>Timelines reviewing committee

### Amendments/ Substantial Amendments (SA)

**Ethical review mandatory for**
Any substantial amendments

**Responsible for notification of SA**
Sponsor
Manufacturer acting as sponsor

**Timeline Ethical review of SA (max nr days)**
35
**Additional Information**

Submission format:
The signed cover letter must be in hard copy for the submission of substantial amendments to the METC.
All other documents which are part of a substantial amendment, are to be sent on cd-rom (together with the hard copy cover letter).

**Safety Reporting**

**Reportable AEs**

SAE (Serious Adverse Event)
SADE (Serious Adverse Device Effect)

Investigator shall report SAE to

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**Reporting timeline**

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**Responsible for AE reporting to relevant EC(s)**

Manufacturer acting as sponsor

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

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All other SUSAR must be reported

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SAE/SADE must be reported

Immediately (without delay)

National Standard Reporting form available

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**Reporting format - Options**

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**Preferred reporting format**

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**Guidance on AE reporting procedure**

Related information can be found on the CCMO website in section: Home>Investigators>Types of research>Research with a medical device.

**End of Trial**

**End of trial Declaration mandatory**

Yes

**Responsible for End of trial Declaration**

Sponsor
Manufacturer acting as sponsor

**Regular Termination - Declaration timespan (max nr days)**

Not specified

**Timespan counted from**

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

Not specified
### Study specific Requirements

#### Sponsor

- **Sponsor - Definition available in national law**
  - Yes

- **Sponsor - Definition (pursuant to national law)**
  - Manufacturer (Sponsor) according to Art 1(d) Medical Devices Decree (Dutch):
    - “The person, legal entity, or the authorised representative of that person, who:
      is responsible for the design, manufacturing, packaging and labeling of a medical device with the aim of marketing said device under one’s own name, regardless of whether these actions are carried out by one and the same person or under the responsibility of a third party; or assembles, packages, processes, updates or labels one or more prefabricated products, or who assigns these products as a medical device with the aim of marketing said device under one’s own name.”

- **Sponsorship mandatory**
  - Yes

#### Study Participants - Informed Consent (IC)

- **Standard IC form (ICF) available**
  - Yes

- **Standard ICF - Additional Information**
  - 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)

- **IC is regulated by law**
  - Yes

- **Informed Consent - Definition/ Requirements**
  - “informed, written, dated and signed consent to take part in a clinical trial”
  - There are special provisions regarding informed consent including consent obtained in vulnerable populations are specified in section 6 of WMO (en)

- **Applicable national legal framework/ Reference**
  - Section 1(1.u) WMO (en): Definition
  - Section 6 of WMO (en): Provisions, vulnerable populatons

#### Study Participants - Vulnerable Population

- **Minors / Children - Studies allowed**
  - Yes
Specific provision
Clinical trials including minors are possible under special provisions. 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>Types of research>Research with minors

Legal framework/Reference (Minors/Children)
Section 4 and 6 of WMO (en)

Incapacitated persons - Studies allowed

Specific provisions
Clinical investigations on MD including minors are possible under special provisions. The WMO applies the “no, unless” principle.

Related information and specific documents (“Non-therapeutic research on minors and incapacitated subjects: ‘no, unless’”) are provided on the CCMO website in section: Home>Investigators>Types of research>Research with incapacitated adults

Legal framework / Reference (Incapacitated persons)
Section 4 and 6 of WMO (en)

Emergency situations - Studies allowed

Specific provisions
Clinical investigations on MD in emergency situations are possible under special provisions.

“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.”

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

Legal framework / Reference (Emergency Situation)
Section 6(4) WMO (en)

Pregnant or breastfeeding women - Studies allowed

Specific provisions
No legal reference

Reimbursement for study participants
Optional

Compensation is limited to/provided for
Inconvenience, Pain, Discomfort
Expenses arising from study participation (e.g. Travel)
Additional Information

- Patients: travel expenses will be reimbursed.
- Healthy volunteers: Compensation is possible and depends on length and load (number of measurements and possible discomfort) of the study. The fee does not depend on the risk of research and is based on the minimum wage. The reviewing committee checks the level of compensation.

Data Protection

Notification to DP Authority/Ombudsmann is mandatory

No

Approval/authorisation required

No

Specific notification timelines before operations start

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Language of notification

—

Notification format

—

Data Protection Authority/Agency - Contact Details

Dutch Data Protection Authority DPA (College Bescherming Persoonsgegevens, CBP)

Phone

(+31) - (0)70 - 888 85 00

Fax

(+31) - (0)70 - 888 85 01

Web address

https://www.cbpweb.nl/en/

Address

PO Box 93374

ZIP/City

2509 AJ DEN HAAG

Country

Netherlands (NL)

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.

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

### 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)

## Insurance

### Liability insurance or alternative arrangements for damages mandatory for

- Investigator(s)
- Manufacturer
- Study participants

### Responsible for covering insurance

- Sponsor
- Manufacturer acting as sponsor

### Applicable national legal framework/ Reference

- Article 13(3) Medical Devices Decree (Dutch)
- Insurance Decree (Verzekeringsbesluit) - 1th of July 2015

### Additional Information

The manufacturer must have a valid liability insurance to cover any harm caused by the clinical investigation (pursuant to Article 13(3) Medical Devices Decree (Dutch))

The adapted Insurance Decree (Verzekeringsbesluit) came into force as of the 1th of July and applies to research issued a positive decision by an accredited MREC or the CCMO after the 1st of July 2015. The Insurance Decree contains the rules for the obliged insurance for research subjects.

Related details are provided on the CCMO website in section: Home>Investigators>Standard research file (G. Insurance information) and Home>News archive>Consequences of the new Insurance Decree and CCMO Directive External Review as of 1st July 2015

Amongst the changes is the new rule that the sponsor ensures that any potential damages for all participating human subjects of a research are covered and research subjects who participate in multicentre research in the Netherlands must be covered by a single research subject insurance. Research applicants are also required to submit a Research subject insurance declaration.

## Quality Assurance/Quality Control (QA/QC)

### Monitoring

- Compulsory

### Audit by sponsor

- Optional

### Standard Operating Procedures (SOPs)

- Optional

### Additional Information

This depends on the risk classification of the study!

## National legislation

### General Information:

- Applicable Legislation & Conventions

### Official website providing relevant national legislation available

- Yes
### Clinical Trials on IMPs in Humans

**Applicable national regulations**

- **Transposition of (GCP) Directive 2005/28/EC**
- **Other applicable regulations/ implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)**

Medical Devices Act /Wet op de medische hulpmiddelen (Dutch)

### Investigations on Medical Devices

**Applicable national regulations**

General Act(s) on Medical/Clinical Research in Humans
National Act on Medicinal Products and Medical Devices
Other

**Act on Medical Devices (or comparable national legal framework)**

Medical Research Involving Human Subjects Act -Unofficial english translation: WMO (en)/Wet medischwetenschappelijk onderzoek met mensen- WMO (Dutch)
(Provisions of Division 5A do not apply!)

### 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

**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)

### Definition

**MD/MD Investigation**

**MD - Definition available in national law**

Yes

**MD - Definition**

see Art 1 Medical Device Act (Dutch)

**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.