Medical Devices - DENMARK

Competent authority

Contact Details

Contact Name 1

Danish Medicines Ageny DKMA/ Lægemiddelsstyrelsen

Contact Name 2

Section for Medical devices

Phone

+45 72 22 74 00

Email General

sst@sst.dk

Email Department

med-udstyr@dkma.dk

Address

Axel Heides Gade 1

ZIP/City

2300 Copenhagen S

Country

Denmark (DK)

Web address

http://sundhedsstyrelsen.dk/en/

Additional Information

Combination Studies:
Email/ Section for Clinical Trials (medicinal products) kf@dkma.dk.

Trial Authorisation / Registration / Notification

Regulatory and ethics bodies involved in approval process

Competent Authority/-ies (CA)
Ethics committee(s)
Agency for data protection

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

–

CE-marked MD used within label are exempted from any notification obligation to CA

Yes

Additional Information

Clinical investigations of CE marked devices utilised for their intended purpose do require notification to EC only!

NB! Combination studies: If the investigation includes an evaluation of medicinal products, the clinical investigation may be classified as a clinical trial of medicinal products and require authorisation by the DHMA unit for clinical trials

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

In parallel

Submission of Application

Responsible for study submission

Sponsor
Legal representative

Entitled to study submission

–

Prerequisites for submission

–

Guidance on submission of application available

Yes

Guidance on submission of application

A comprehensive guidance (“Guidance on application for the authorisation for clinical investigation of medical devices”) is available on the CA website in section:
Medicines & medical devices / Medical devices / Clinical investigations / Application

Submission Format

Format option(s)

Email
Regular mail
Data carrier (CD-rom/DVD)
Via Eudralink (EMA)

Preferred format

–

Standard application form available

Yes

Standard application form

The standard application form to be used: “Application form for the authorisation of clinical investigations of medical devices”
Available on CA website in section: Medicines & medical devices / Medical devices / Clinical investigations / Application

Guidance on submission format

A comprehensive guidance on application format and required documentation (“Guidance on application for the authorisation for clinical investigation of medical devices”) is available on the CA website in section:
Medicines & medical devices / Medical devices / Clinical investigations / Application

Additional Information

ad Format options: :
One copy of all required documents with relevant signatures should be submitted via:
(1) CD-ROM (Preferred I): a signed cover in paper form and as a PDF file on the CD-ROM)
(3) Via Eudralink (Preferred II):
- documentation sent to med-udstyr@dkma.dk without a password
- register as Eudralink user via https://eudralink.ema.europa.eu/
(3) Regular mail
(4) Email: For submission of supplementary information (NB! Limited data size)

Language of Submission

Language(s) of application

Danish
English

Preferred language of application

–

English accepted

–

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

Application fees (January 2015)
• Class I, IIa, IIb devices (not implantable devices and devices intended for long term use): 20,297 DKK (≈ € 2720)
• Class IIb devices (implantable devices and devices intended for long term use): 25,994 DKK (≈ € 3480)
• Class III devices and active implantable devices: 25,994 DKK (≈ € 3480)
• In vitro diagnostic medical devices (in vitro medical devices intended to come in direct or indirect contact with the human body): 20,297 DKK (≈ € 2720)
• Changes/amendments to authorised clinical investigation plans: 5,036 DKK (≈ € 670)

No waiver possible as the DKMA has no statutory authority to grant exemption from the fee

Applicable fees are published on the website in section
Medicines & medical devices / Medical devices / Clinical investigations / Fees for clinical investigations (en) or in the Ministry of Health and Prevention's Executive Order for fees on medical devices (

Waiver for academic (non-commercial) studies possible

No

Payment requirements (timelines)

After receipt of invoice

	Official guidance on required fees available Yes **Official guidance on required fees** Applicable fees are published on the website in section: Medicines & medical devices / Medical devices / Clinical investigations / Fees for clinical investigations (en) **National legal framework in place** Yes **Applicable national legal framework/ Reference** Ministry of Health and Prevention's Executive Order for fees on medical devices 2013 **Additional Information** Fees for clinical trials should be paid within one month after receipt of the invoice.
Timelines Authorisation	**General timespan (max nr days)** 60 **Mode of approval (General)** – **Clock-stop possible if complementary information requested** No **Timespan counted from** Confirmation of formal completeness **Additional Information** Information on completeness provided by CA: within 14 days. The CA's evaluation of an application may take place at the same time as the evaluation by the system of research EC.
Amendments/ Substantial Amendments (SA)	**Notification mandatory for** Any substantial amendments **Authorisation mandatory for** Substantial amendments (as determined by CA) **Responsible for submission of SA** Sponsor **Standard notification form available** Yes **Standard notification form** Standard application form for amendments to be used: “Application form for the authorisation to make changes and amendments to the clinical investigation” available on the DHMA website in section: Medicines & medical devices / Medical devices / Clinical investigations / Application / Amendments to Application (Forms) **Timeline for approval of SA (max nr days)** –

Guidance on submission of SA

A list provided on DKMA website shows examples of amendments that require authorisation or notification only (Section: Medicines & medical devices / Medical devices / Clinical investigations / Application / Amendments to Application)

Further, a detailed guidance is available on the CA website in section: Medicines & medical devices / Medical devices / Legislation and Guidance / Guidance / Guidance on application

Safety Reporting

Responsible for AE reporting to CA

Sponsor

Sponsor must declare reportable events to

National CA
CA(s) of EU&EFTA Member States concerned

Reportable AEs

SAE (Serious Adverse Event)
SAE (Serious Adverse Event) - Near Incidents

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

–

All other SUSARs

–

SAE /SADE must be reported

Immediately, not later than 2d (SAE indicating an imminent risk of death, serious injury, or serious illness)
Immediately, not later than 7d upon first knowledge (any other SAE)

National standard reporting form available

–

Standard Reporting Form

The forms are available in section Medicines & medical devices / Medical devices / Clinical investigations / Application:
(1) Notification of serious adverse events and near-incidents with medical devices during a clinical investigation
(2) EU Commission's SAE Reporting form (Excel)

Notification format:
Per Email to med-udstyr@dkma.dk

Reporting format - Options

Email

Preferred format

–

Provision of Annual safety report mandatory

Yes

Annual safety report shall be provided by sponsor to

National CA

Guidance on AE reporting procedure

The conditions for AE reporting stipulated by the DHMA correspond to the guidance provided in the EU Commission guidelines on reporting of adverse events ”Guidelines on medical devices. Clinical investigations: Serious adverse event reporting” MEDDEV 2.7/3.

Additional Information

All other adverse events (not categorised as „serious“) must be declared in the final report.

Investigator shall report SAE to

–

Reporting timeline

–

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)

90

Timespan counted from

–

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

15

Standard Declaration form available

Yes

Standard Declaration form

Standard form to be used “Notification of the completion of clinical investigations of medical devices” is available on the CA website in section: Medicines & medical devices / Medical devices / Clinical investigations / Application

Guidance on End of trial declaration available

Yes

Guidance on End of trial declaration

Detailed guidance is available on the CA website in section: Medicines & medical devices / Medical devices / Legislation and Guidance / Guidance / Guidance on application

Ethics committee

Contact Details

Contact Name 1

The National Committee for Health Research Ethics - Den Nationale Videnskabsetiske Komité (DNVK)

Phone

+45 72 26 93 70

Address

Holbergsgade 6

ZIP/City

1057 København K

Country

Denmark (DK)

	E-Mail DKetik@DKetik.dk **Web address** http://www.dnvk.dk/forskere/ **Additional Information** The national committee (DNVK) provides information on the system of research ethics committees' electronic application and the regional research Ethics Committees.
Ethical Review – General	**Submission for Ethical review mandatory for** Clinical investigations on MD **Submission to CA and EC to be performed in the following order** In parallel **Additional Information** Clinical investigations of MDs, regardless of whether the device are CE approved or not, shall be notified to the relevant regional EC **Regulatory and ethics bodies involved in approval process** –
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** Regional EC (competent for the area where investigator is located) **Additional Information** Clinical investigations of MDs, regardless of whether the device are CE approved or not, shall be notified to the relevant regional EC where the investigator is located.
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Regional EC (competent for the area where coordinating investigator is located) authorized to issue a single opinion **Submission of application required to** Regional EC (competent for the area where coordinating investigator is located) authorized to issue a single opinion **Additional Information** The co-ordinating investigator submits the application for a multi-site study to the regional scientific ethical committee of the area in which he/she is operating. This regional committee must make its decision, which forms the basis for an opinion, and then informs the other regional committees and the Danish National Committee for Biomedical Research Ethics.
Submission of Application	**Responsible for study submission** Sponsor Principal Investigator **Entitled to study submission** – **Prerequisites for submission / approval** – **Guidance on study submission available** Yes

	Guidance on study submission The notification to the research ethics committee shall meet the requirements stated in „Guidelines about Notification etc. of a Biomedical Research Project to the Committee System on Biomedical Research Ethics., No 9154, 5 May 2011“ **Applicable national legal framework/ Reference** Section 14 & 15 of the Committee Act
Submission Format	**Format option(s)** Online portal **Preferred format** – **Online portal** Via DKMAnet: Only one application to the common submission portal. (Currently the use of the DKMAnet is not mandatory, but in future it will be. Exact date is not yet decided) **Guidance on submission format** Further details are provided on the DNVK website in section: Notification of clinical trial of medicinal products The notification to the research ethics committee shall meet the requirements stated in „Guidelines about Notification etc. of a Biomedical Research Project to the Committee System on Biomedical Research Ethics.
Language of Submission	**Language(s) of application** Danish English **Preferred language of application** – **English accepted** – **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 study participant** –
Submission Fees	**Fees for Ethical review mandatory** Yes **Fees for Ethical review** Notification fee for projects: General: DKK 4000 (≈ € 540) For a supplementary protocol: DKK 1500 (≈ € 200)
Timelines Ethical Review	**General timespan for single-centre studies (max nr days)** 60 From date of receipt of valid application

	General timespan for multi-centre studies (max nr days) 60 From date of receipt of valid application **External expert advice required: Timespan (max nr days)** – **Timespan counted from** – **Additional Information** The CA's evaluation of an application may take place at the same time as the evaluation by the system of research EC. The contents of the clinical investigation plan, which forms the basis for the evaluation of CA and EC, shall be identical.
Amendments/ Substantial Amendments (SA)	**Ethical review mandatory for** Any substantial amendments to the study protocol **Responsible for notification of SA** Principal Investigator Investigator **Standard notification form** Standard amendment notification form to be used. Format: electronically (using digital signature) **Timeline Ethical review of SA (max nr days)** 35 From date of receipt of valid application **Guidance on submission of SA available** Yes **Guidance on submission of SA** Further details on the notification of amendments and the characterisation of substantial amendments are provided in Section 6.0 of the Guidelines about Notification etc. of a Biomedical Research Project to the Committee System on Biomedical Research Ethics. **Applicable national legal framework/ Reference** Section 27 of the Committee Act
Safety Reporting	**Adverse Events (AE) - Definitions (pursuant to national law)** Definitions: • SAE: According to the EU Commission guidelines • SAE- Near incidents: include situations in which SAEs could have occurred if suitable action had not been taken or if circumstances had been less fortunate. • SAE- Malpractice: SAEs caused by imprecise or incomplete results from diagnostic equipment leading to incorrect diagnosis, delayed diagnosis or delayed or incorrect treatment **Reportable AEs** – **Investigator shall report SAE to** –

	Reporting timeline – **Responsible for AE reporting to relevant EC(s)** – **SUSAR being life-thereatening or leading to death must be reported** – **All other SUSAR must be reported** – **SAE/SADE must be reported** – **National Standard Reporting form available** – **Reporting format - Options** – **Preferred reporting format** –
End of Trial	**End of trial Declaration mandatory** Yes **Responsible for End of trial Declaration** Sponsor Investigator **Regular Termination - Declaration timespan (max nr days)** 90 **Timespan counted from** Last patient - last visit in the respective country **Early/premature Termination - Declaration timespan (max nr days)** 15 **Reasons for early termination shall be clearly stated** Yes **Standard Declaration form available** Yes **Standard Declaration form** Standard notification form (in Danish) available and downloadable on the website of the National Research EC in Section: Reporting of adverse reactions, completion of trials, etc. Submission format: electronically using digital signature **Applicable national legal framework/ Reference** Section 31(1&2) of the Committee Act **Additional Information** The investigator and the sponsor must jointly notify the EC.

Study specific Requirements

Sponsor	**Sponsor - Definition (pursuant to national law)** The sponsor is the person, institution or company being responsible for the initiation, management and completion of a clinical investigation (it is usually the manufacturer of the device). **Sponsorship mandatory** Yes **Legal representative based in the EU/EEA is mandatory where Sponsor is located outside EU/EEA:** Yes
Study Participants - Informed Consent (IC)	**IC is regulated by law** Yes **Informed Consent - Definition/ Requirements** Definition is provided in section 2(10) of the Committee Act. It is a decision to participate in a research project which has been made upon due information on the nature, significance, implications and risks of the project and receipt of suitable documentation. The decision is made voluntarily by a person who is capable of giving his or her consent. The consent shall be in writing, dated and signed or provided using an electronic signature. Specific requirements apply to vulnerable populations. The requirements on written information, application, notification and reporting is described in detail in the 'Guidelines about Notification etc. of a Biomedical Research Project to the Committee System on Biomedical Research Ethics'. **Applicable national legal framework/ Reference** The procedures of how to inform and obtain consent from subjects participating in clinical trials are regulated by: (1) Executive Ministerial Order No 806 of 12 July 2004 on Information and Consent at Inclusion of Trial Subjects in Biomedical Research Projects (2) Committee Act
Study Participants - Vulnerable Population	**Minors / Children - Studies allowed** Yes Special provisions apply **Legal framework/Reference (Minors/Children)** • Art 20 & 21 of Ministerial Order No 806 • Part 3, section 9 and Part 5, section 17&19 of the Committee Act • Further details on „Trials with children and young people under the age of 18“ are provided in in section 4.4 of the 'Guidelines about Notification etc. of a Biomedical Research Project to the Committee System on Biomedical Research Ethics'. **Incapacitated persons - Studies allowed** Yes Special provisions apply **Legal framework / Reference (Incapacitated persons)** • Art 22 of Ministerial Order No 806 • Part 3, section 3-5 of the Committee Act • Further details are provided in in section 4.4 of the 'Guidelines about Notification etc. of a Biomedical Research Project to the Committee System on Biomedical Research Ethics'.

Emergency situations - Studies allowed

Yes
Special provisions apply

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

Yes
Special provisions apply

Conditions allowing trial participation in emergency setting without prior consent

A clinical investigation of MD may be allowed without prior consent if the following conditions are met:
- the nature of the research project requires that it can only be undertaken in acute emergency situations (the physical/mental condition is a necessary characteristic element of the research project) where the trial subject is unable to give his/her informed consent and it is not possible to obtain proxy consent
- it may improve the health of the person in the long term
- it may improve the condition of other patiens with the same disease and the intervention poses minimal risk and burden to the patient.
- The investigator shall as soon as possible thereafter seek to obtain informed consent or proxy consent.

This is normally applicable to trials involving individuals who are temporarily incapacitated, e.g. unconscious.

NB! This shall not apply to clinical research with medicinal products!

Legal framework / Reference (Emergency Situation)

• Section 11 of the Committee Act
• Further details are provided in Section 4.6.1 of the Guidelines about Notification etc. of a Biomedical Research Project to the Committee System on Biomedical Research Ethics.

Pregnant or breastfeeding women - Studies allowed

No national legal framework available

Legal framework / Reference (Pregnant or breastfeeding women)

There are no common provisions mentioned in Danish law regarding the inclusion of pregnant or lactating women.

Specific requirements in regard to contraception must be considered when including fertile women in clinical trials
(see “Guidance on application for the authorisation for clinical investigation of medical devices” available on CA website in section: Medicines & medical devices / Medical devices / Clinical investigations / Application

National legal framework for protection of vulnerable populations in place

Yes

Applicable legal framework / Reference (Vulnerable Population)

1) Ministerial Order No 806
(2) Committee Act
(3) Further details on the inclusion of vulnerable population in a clinical trials are provided in Section 4.6.2 of the Guidelines about Notification etc. of a Biomedical Research Project to the Committee System on Biomedical Research Ethics.

Study Participants - Compensation & Reimbursement

Reimbursement for study participants

Depends on study population (healthy subjects or patients)

Compensation is limited to/provided for

Inconvenience, Pain, Discomfort
Expenses (e.g. transportation, meals, and others such as salary lost)

Additional Information

In general a distinction is made between compensation for documented loss of earnings or for documented transportation costs and inconvenience compensation, which relates to the invasiveness, duration, pain and discomfort of the trial. Healthy trial subjects may receive all this types of remuneration.

Trial patients, who participate in a trial because they have a disorder or condition which is required for participation in the trial, cannot be offered inconvenience compensation.
However model trial patients may receive the same types of remuneration as healthy trial subjects. These trial subjects are patients but there must be no possible treatment benefit of trial participation.

Further details are provided in the 'Guidelines for remuneration or other payment for voluntary trial subjects, Appendix 6 in the Guidelines about Notification etc. of a Biomedical Research Project to the Committee System on Biomedical Research Ethics'

Study Participants - Recruitment & Trial Outcome

Additional Information

Publication obligation: publication of negative, inconclusive and positve results is mandatory according to section 20(8) Committee Act.

Data Protection

Notification to DP Authority/ Ombudsmann is mandatory

Yes

Approval/ authorisation required

Not specified

Specific notification timelines before operations start

–

Language of notification

–

Notification format

–

Data Protection Authority/ Agency - Contact Details

Danish Data Protection Agency

Phone

+45 3319 3200

Web address

http://www.datatilsynet.dk/english/

Country

Denmark (DK)

Additional Information

Clinical trial on IMP shall also be notified to the Danish Data Protection Agency (according to the Act on Processing of Personal Data).
This may take place at the same time as the application to the CA.
More information on notification requirements can be obtained by the Agency.

If information from patients' records is to be used – in register research projects without the use of biological material – an application for such approval shall be submitted to the DKMA.

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

–

Insurance

Liability insurance or alternative arrangements for damages mandatory for

Investigator(s)
Sponsor
Study participants

Responsible for covering insurance

–

Applicable national legal framework/ Reference

(1) Section 20(7) of the Committee Act
(2) Danish Act on the Right to Complain and Receive Compensation (2009) and Danish Liability for Damages Act (2005): regulate the conditions for paying compensation

Additional Information

Insurance or other compensation arrangemens must be in place to cover any harm or injury of the study participant/ patient as well as the liability of the investigator and the sponsor.

Persons taking part in biomedical trials that do not form part of the diagnosis or treatment of their illness shall also be regarded as patients. The same shall apply to donors from whom tissue and other biological material are taken.

The website of the Patient Compensation Association deals with compensation claims for patients injured in connection to treatment by the Danish Health Service. It als covers drug injury cases, i.e. cases where patients are injured because of adverse reactions to the medicines they take

The system is supplemented by private compensation and reimbursement schemes.

Quality Assurance/ Quality Control (QA/QC)

Monitoring

Compulsory

Audit by sponsor

Optional

Standard Operating Procedures (SOPs)

Optional

National legislation

General Information: Applicable Legislation & Conventions

Official website providing relevant national legislation available

Yes

Official website providing relevant national legislation

The website of the Danish Medicines Agency provided applicable regulations and guidance documents for medical devices in Denmark (Section: Medicines & medical devices / Medical devices / Legislation and Guidance)

Official governmental legal database available

Yes

Official governmental legal database

Retsinformation.dk: Danish national system for legal texts such as Acts, Executive Orders and Circulars (in Danish only).

Investigations on Medical Devices

Applicable national regulations

National Act on Medical Devices
Transposition of EU Directives on MD
Other

Act on Medical Devices (or comparable national legal framework)

• Act no. 1046 of 17 December 2002 on medical devices

Transposition of Directive 90/385/EEC

• Active implantable medical devices:
The Ministry of Health’s executive order no. 1264 of 15 December 2008 on active implantable medical devices

Transposition of Directive 93/42/EEC

• Medical Devices:
The Ministry of Health’s executive order no. 1263 of 15 December 2008 on medical devices

Transposition of Directive 98/79/EC

• In vitro diagnostic medical devices:
The Ministry of Interior and Health's executive order no. 1269 of 12 December 2005 on in vitro diagnostic medical devices

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

• The Danish Medicines Agency’s executive order no. 292 of 19 March 2010 on the application for the authorisation for clinical investigation of medical devices on human subjects.
It covers specific regulatory requirements for clinical investigations of medical devices

• Ethical Review:
Lov om et videnskabsetisk komitésystem og behandling af biomedicinske forskningsprojekter / Act on Research Ethics Review of Health Research Projects: unofficial translation, hereinafter referred to as the Committee Act (en)

Radiation & Radiotherapy

Use of radiation or radioactive compounds - Specific requirements

Yes

Applicable legal framework

Danish Act on the Use of X-rays
Danish Act on Use of Radioactive Substances
Danish Act on Nuclear Installations

	Additional Information Approval is required in case that radiation is used in the clinical trials More information on notification and approval may be obtained by contacting the institute: The National Institute of Radiation Protection Knapholm 7 2730 Herlev Denmark Tel. +45 4454 3454 24-hour hotline: +45 4494 3773 Fax +45 7222 7417 Email sis@sis.dk (Head of Division: Mette Karin Øhlenschlæger Email: moe@sis.dk, Phone +45 4454 3481) Contact is provided on the CA website in section: About us / Contact / Contact the Danish Health Authority
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** Data Protection Law: Lov om behandling af personoplysninger/ Act on Processing of Personal Data - Act No. 429 of 31 May 2000 (unofficial english version; updated with amendments until Dec 2012)
Insurance	**Specific requirements** Yes **Applicable legal framework** Danish Act on the Right to Complain and Receive Compensation (2009) Danish Liability for Damages Act (2005)
CA operations/ Fees	**Separate legal framework available** Yes **Applicable legal framework** The Ministry of Health’s Executive Order No. 1546 of 18 December 2014 concerning fees for medical devices

Definition

MD/MD Investigation	**MD - Definition available in national law** Yes **MD - Definition** Definitions are provided in Chapter 1 of The Ministry of Health’s executive order no. 1263 of 15 December 2008 on medical devices (in Danish only). **Investigation of MD - Definition available in national law** Yes **Investigation of MD - Definition** „Any investigations on humans which serve the purpose of verifying or testing the safety and/or performance of a medical device“ (Definition according to part 2, section 2 of the Committee Act and Chapter 1 of The Ministry of Health’s executive order no. 1263 of 15 December 2008 on medical devices)