

**CONDUCTING MEDICAL DEVICE
CLINICAL INVESTIGATIONS
COUNTRY BY COUNTRY REQUIREMENTS
EUROPE**



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List of Abbreviations

AIMDD	Active Implantable Medical Device Directive
CA	Competent Authority
CI	Clinical Investigation
CIP	Clinical Investigation Plan
CRF	Case Report Form
Docs	Documents
REC	Research Ethics Committee
GCP	Good Clinical Practice
CIB	Clinical Investigator's Brochure
IFU	Instructions For Use
IVDD	In Vitro Diagnostic Directive
MDD	Medical Device Directive

FOREWARD

The contents of this document are based on the information received from each of the countries included. Sometimes the information provided is not accurate, can be open to interpretation, or updated. It is therefore important that when you embark upon any clinical investigation (or post market study) you contact the appropriate Competent Authority and or Research Ethics Committee.

AUSTRIA

Competent Authority Contact Information	
Contact Person	Dr. Wolfgang Ecker, Dr. Martin Renhardt, Ing. Andreas Gutruf
Address	Federal Ministry of Health & Women, Medical Device Dept., Radetzkystrasse 2, A-1030 Vienna, Austria
Telephone	+43 1 711 00 42 06, +43 1 711 00 44 87, +43 1 711 00 46 02, (Secretariat)
Fax	+43 1 711 00 42, +43 1 713 44 04 1432
Email	meddev@bmgf.gv.at
Website	www.bmgf.gv.at
Applicable Regulations	
AIMDD	90/385/EC as transposed into national law
MDD	93/42/EC Austrian Medical Device Act, BGBl. Nr.657/1996, curr.vers
IVDD	98/79/EC as transposed into national law
Other regs/guidelines	Clinical Investigations must be conducted and notified according to §40 of the Austrian Medical Device Act, BGBl. Nr. 657/1996, curr.vers Clinical Investigations to be conducted according to ISO 14155
CA Notification Requirements	
<ul style="list-style-type: none"> • Notification required for all Clinical Investigations • Research Ethics Committee approval required before submission to CA • Documents to be submitted include, CIP, CRF, CIB, REC approval, consent docs, insurance, investigators qualifications, statement of conformity with directive, any further safety information particularly if device includes parts of human or animal origin • 60 day waiting period obligatory • No fees • Standard notification form available in English • Language German/English, all information given to the patient must be in German <p>Notification to be sent to; Federal Ministry for Social Security and Generations, Department VIA/22 – Medical Devices, Radetzkystrasse 2, A-1031 Vienna; Austria. Tel: +43 1 711 00 ext. 4206 or 4487 or 4602, Fax: + 43 1 71100 4217</p>	
Ethics Committee Information	
<ul style="list-style-type: none"> • Research Ethics Committee approval required before submission to CA • Documentation to submit includes, CIP & summary, consent documents, CE certificate for CE marked products, CRFs, IFU, insurance policy, all documents must be in German • Cost approximately €1450 may vary between committees • Submit to committee attached to hospital where study is to be conducted • www.ethikkommission.at 	
Comments/Practical Experience	
<ul style="list-style-type: none"> • Device labelling in German • Insurance required • Hospital may charge for the study • Decision on who will pay for clinical trial devices will depend on the individual healthcare providers 	

BELGIUM

Competent Authority Contact Information	
Contact Person	Head of Medical Device Unit – Mrs. Paule Jacquain Co-ordinator of Medical device Unit – Mr. Philippe Bauwin
Address	SPF Santé Publique, DG Protection de la Santé Publique: Médicaments Service des dispositifs médicaux, Cité Administrative de l' Etat – Quartier, Vésale 320, Rue Montagne de l' Oratoire, 20 BP 3, B- 1010 Brussels, Belgium
Telephone	+ 32 2 210 48 99
Fax	+ 32 2 210 49 10
Email	meddev@afigp.fgov.be
Website	www.afigp.fgov.be (Direction Général) www.health.fgov.be (Service Public Fédéral)
Applicable Regulations	
AIMDD	90/385/EC as transposed into national law
MDD	93/42/EC as transposed into national law
IVDD	98/79/EC as transposed into national law Contact for IVDD different to other devices details below; Dr. Pharm Jean-Calude Libeer & Dr. Anne Van Nerom, DVM Scientific Institute Public Health – Louis Pasteur, Department of Clinical Biology, J Wytsmanstraat, 14 B- 1050 Brussels, Belgium Tel: + 32 2 642 55 21, Fax: + 32 2 642 56 45 Email: jean.claude.libeer@iph.fgov.be & anne.vannerom@iph.fgov.be
Other regs/guidelines	Clinical Investigations are controlled by the Belgian Ministry of Social Affairs, Public health and Environment Pharmaceutical Inspectorate Department of Medical Devices
CA Notification Requirements	
<ul style="list-style-type: none"> • Notification required for all Clinical Investigations • Research Ethics Committee approval required before submitting to CA • Documents to be submitted include, CIP, CRF, IB, EC approval, consent docs, insurance, investigators' qualifications, statement of conformity with directive • 60 day waiting period obligatory • Fees are charged for notification • Standard notification form available in English • Language of documents submitted can be German, French, Dutch/Flemish or English 	
Ethics Committee Information	
<ul style="list-style-type: none"> • Documentation to submit includes, CIP & summary, consent documents in French, Dutch/Flemish & German, CE certificate for CE marked products, CRFs, IFU, insurance policy • Cost may vary between committees • For multi-centre clinical investigations, the sponsor applies to the Lead Ethics Committee and non-Lead Ethics Committees in parallel. Lead Ethics Committee approves the clinical investigation and the non-Lead Ethics Committees only review the individual Investigator and site's ability to undertake the clinical investigation. Once n-LECs have approved a specific site they inform the LEC • Most documents can be in English (except consent docs and patient specific docs) 	

Comments/Practical Experience

- Device labelling in French, German, Dutch/Flemish
- Insurance required
- Hospital may charge for the study
- Devices for clinical investigation must not be sold to sites

BULGARIA

Competent Authority Contact Information	
Contact Person	
Address	Bulgarian Drug Agency, 26 Yanko Sakazov Blvd, 1504 Sofia, Bulgaria
Telephone	+35 9 2 943 4046
Fax	+35 9 2 943 4478
Email	bda@bda.bg
Website	www.bda.bg
Applicable Regulations	
AIMDD	90/385/EC not currently transposed into national law
MDD	93/42/EC not currently transposed into national law
IVDD	98/79/EC not currently transposed into national law
Other regs/guidelines	Several local laws govern clinical research; The Law for Drugs and Pharmacies in Human Medicine, Regulation N 14 (Conditions and Procedures for Conducting Clinical Trials of Medicinal Products on Humans Beings)
CA Notification Requirements	
<ul style="list-style-type: none"> • Notification required for all Clinical Investigations • Research Ethics Committee approval required before submission to CA • Documents to be submitted include, CIP, CRF, IB, EC approval, consent docs, insurance, investigators qualifications, statement of compliance with the Law of Drugs and Pharmacies in Human Medicine • Standard notification form available in English or Bulgarian (same form for drug clinical investigations as it is for devices) • Notification form may be completed in English but all other docs must be in Bulgarian • No fees charged by the CA • BDA checks the application against GCP and then forwards the details to the Specialised Committee for Approvals of Conducting Clinical Trials (SCACCT) • BDA approval takes 1 month and SCACCT approval takes a further 9 weeks • Both approvals are required before commencing the Clinical Investigation 	
Ethics Committee Information	
<ul style="list-style-type: none"> • Documentation to submit includes, CIP, CIB, CRF and all patient docs • Submit to Local Research Ethics Committee at each hospital where the clinical investigation is to be conducted • Central Ethics committee only acts as an ombudsman between applicants and the Local Ethics Committees if the need arises • All documents in Bulgarian • Ethics Committee approval required before submission to CA 	
Comments/Practical Experience	
<ul style="list-style-type: none"> • Device labelling in Bulgarian • Insurance required • Hospital may charge for the study 	

CYPRUS

Competent Authority Contact Information	
Contact Person	Charalambos Yiannakkaras
Address	Cyprus Medical Device Competent Authority, John Kennedy 18, JUKI Building, 1446 Pallouriotissu, Nicosia, Cyprus
Telephone	+35 7 22 468429
Fax	+35 7 22 468427
Email	CYiannakkaras@mphs.moh.gov.cy
Website	
Applicable Regulations	
AIMDD	90/385/EC as transposed into national law
MDD	93/42/EC as transposed into national law
IVDD	98/79/EC as transposed into national law
Other regs/guidelines	
CA Notification Requirements	
<ul style="list-style-type: none"> • Notification required for all Clinical Investigations • Ethics Committee approval required before submission to CA • No fees charged by the CA • Standard notification form available in English or Greek • Documents to be submitted are according to the applicable EU regulation • 60 day waiting period obligatory 	
Ethics Committee Information	
<ul style="list-style-type: none"> • Documentation to be submitted includes, CIP, CIB, CRF and all patient docs • Submit to the Cyprus National Bioethical Committee • Ethical approval required before submission to the CA 	
Comments/Practical Experience	
<ul style="list-style-type: none"> • Device labelling in English and Greek • Insurance is not required by law or by the CA however it may be a local requirement of hospitals • Hospital may charge for the study 	

DENMARK

Competent Authority Contact Information	
Contact Person	Halina Magierkiewicz Mr. Søren Bøgestrand
Address	Danish Medicines Agency, Medical Devices Section, Axel Heides Gade 1, DK-2300 København S, Denmark
Telephone	+ 45 44 88 95 95
Fax	+ 45 44 88 95 99
Email	Med-udstyr@dkma.dk
Website	www.medicinskudstyr.dk & www.dkma.dk
Applicable Regulations	
AIMDD	90/385/EC as transposed into national law
MDD	93/42/EC as transposed into national law
IVDD	98/79/EC as transposed into national law
Other regs/guidelines	Many guidelines on ethical aspects of studies available at www.forsk.dk
CA Notification Requirements	
<ul style="list-style-type: none"> • Notification required for all clinical investigations • Submission to Ethics Committee can be done at the same time as CA • DKK6,730 charged for new notification • Standard notification form available in English • Documents to be submitted include CIP & summary, patient consent docs, CRFs, IB, application letter and statement of conformity with the directive. • All patient docs must be in Danish, all others can be in English OR Danish, not a mixture of both. • Approval usually given within 30 days • No obligatory waiting period 	
Ethics Committee Information	
<ul style="list-style-type: none"> • Submit to the regional ethics committee of the principal site in Denmark which ensures that the submission is made available to any other appropriate regional ethics committees. • Documentation to submit includes, CIP & summary, consent docs, certificate for CE marked products, CRFs, IFU and insurance policy • All documents in Danish • Cost approximately DK4,000 and additional fee of DK1,500 for each centre in a multi-centre study • Website www.forsk.dk • The Danish Scientific Central Ethics Committees review any appeals against decisions of Regional Ethics Committees. • Contact details for The Danish Scientific Central Ethical Committee are; Randersgade 60, DK-2100 Copenhagen, Denmark. Tel: + 45 3544 6200, Fax: + 45 3544 6201 	
Comments/Practical Experience	
<ul style="list-style-type: none"> • Device labelling in Danish • Insurance required • Hospital may charge for the study • No reimbursement for clinical investigation devices • No waiting period once approval is received from EC/CA 	

FINLAND

Competent Authority Contact Information	
Contact Person	Mr. Petri Pommelin – Head of Department
Address	National Agency for Medicines Medical Devices , Mannerheimintie 1036, P. O. Box 55, FIN-00301, Helsinki, Finland
Telephone	+ 35 89 47 33 41, +35 89 47 33 42 46
Fax	+ 35 89 47 33 42 66, +35 89 714 469
Email	kirjuarno@nam.fi
Website	www.nam.fi
Applicable Regulations	
AIMDD	90/385/EC as transposed into national law
MDD	93/42/EC as transposed into national law
IVDD	98/79/EC as transposed into national law
Other regs/guidelines	Normative Guideline 1/2001 Clinical Investigations on Medical Devices available from CA
CA Notification Requirements	
<ul style="list-style-type: none"> • Notification required for all clinical investigations • Ethics Committee approval required before submission to CA • Guidelines and standard application form available in English • Documents to be submitted include, CIP, CRF, IB, EC approval, consent docs, insurance, investigators qualifications, statement of conformity with the directive • Language English acceptable • 60 day waiting period obligatory • €900 charged for new notification 	
Ethics Committee Information	
<ul style="list-style-type: none"> • Ethics Committee approval required before submission to CA • For international multi-centre clinical investigations submit to Subcommittee on Medical Research Ethics of the Advisory Board and Health Care Ethics (SMRE). Then submit to hospital district Ethics Committees and SMRE will aid. • Single centre clinical investigations only require approval from hospital district ECs • Fees exist and vary between committees • For further information on ethics committees in Finland www.research.fi or contact Ritva Halila at the Ministry of Social Affairs and Health Email:ritva.halila@stm.vn.fi, Tel: +358 9 160 3834 	
Comments/Practical Experience	
<ul style="list-style-type: none"> • Insurance not mandatory but is recommended • Device labelling in Finnish and Russian 	

FRANCE

Competent Authority Contact Information	
Contact Person	Mounia Lekehal, Dr. Jean Claude Ghislain, Dr Luc Denicourt
Address	Agence française de sécurité sanitaire de santé (AFSSAPS) 143-147 boulevard Anatole France 93285 Saint Denis Cedex France
Telephone	+ 33 1 55 87 37 16, + 33 1 55 87 45
Fax	+ 33 1 55 87 37 62
Email	Mounia.lekehal@afssaps.sante.fr , Jean-claude.ghislain@afssaps.sante.fr , luc.denicourt@afssaps.sante.fr
Website	www.afssaps.sante.fr
Applicable Regulations	
AIMDD	90/385/EC as transposed into national law
MDD	93/42/EC as transposed into national law
IVDD	98/79/EC as transposed into national law
Other regs/guidelines	Loi Huriet to be applied for all clinical investigations "Code de la santé publique"
CA Notification Requirements	
<ul style="list-style-type: none"> • Notification required for all clinical investigations • Notify using the form "Déclaration d'intention pour toute investigation clinique portant sur des dispositifs médicaux" x 3 copies along with CIP summary, CIP, CRF, IB, EC approval, consent docs, insurance, investigators qualifications, statement of conformity with directive with non CE marked product, otherwise send CE mark certificate for CE Mark product (list available from AFSSAPS) • No fees • Language French for most documents • Ethics committee opinion required before submission • 60 day waiting period for Class IIb, III and AIMD 	
Ethics Committee Information	
<ul style="list-style-type: none"> • CCPRB = comité consultatif des personnes participant à une recherche biomédicale (Ethics Committee in France), 34 regional 14 in Paris www.inserm.fr for full list of ECs with addresses • EC takes up to 5 weeks to give opinion • Documentation to submit available as a list from the individual ECs • Cost €1450 • Submit to one committee for multi centre sites • Most documents should be in French 	
Comments/Practical Experience	
<ul style="list-style-type: none"> • Device labelling in French • Insurance required by law must be taken out in France • Hospital may charge for the CI and require that hospital approval is received before starting the CI • Devices for clinical investigation must not be sold to sites • If the device involves a product of animal origin the opinion of the Virus Safety group must be obtained before a CI can commence • Investigators have to notify l'Ordre Départemental des Médecins before starting a CI 	

GERMANY

Competent Authority Contact Information	
Contact Person	AIMDD & MDD-Dr. Ekkehard Stösslein
Address	Federal Institute for Drugs and Medical Devices, Kurt Georg, Kiesinger Allee 3, D53175, Bonn, Germany
Telephone	+ 49 228 207 30
Fax	+ 49 228 207 5207
Email	medizinprodukte@bfarm.de
Website	www.bfarm.de , www.dimdi.de , www.zlg.de & www.bmgs.bund.de all useful sites
Applicable Regulations	
AIMDD	90/385/EC as transposed into national law
MDD	93/42/EC as transposed into national law
IVDD	98/79/EC as transposed into national law Contact for IVDD different to other devices details below; Dr. Rüdiger Siekmeier Address and email as above Tel: + 49 228 207 5360, Fax: + 49 228 207 5300 www.bfarm.de & www.pei.de
Other regs/guidelines	None Known
CA Notification Requirements	
<ul style="list-style-type: none"> • Notification required for all clinical investigations • Contact for CIs hummel@dimdi.de or stark@dimdi.de • 60 day waiting period obligatory if EC opinion has not been obtained however, if EC opinion obtained notify and start • Notification electronic via www.dimdi.de website requires registration • No fees • Standard notification form on website, only available in German • Language German • Competent Authorities set up under each German Authority list can be found at www.bfarm.de. Notify CA where Co-ordinating clinical investigator is for multi centre sites 	
Ethics Committee Information	
<ul style="list-style-type: none"> • Submit to Ethics Committee at each hospital. • Documentation to submit includes, CIP & summary, consent docs in German, CE certificate for CE marked products, CRFs, IFU, insurance policy • Cost varies between committees • Private ECs registered under German law can perform review, list of registered ECs can be found at www.bfarm.de • Many institutions also require review by their own committees in addition to a private EC review 	
Comments/Practical Experience	
<ul style="list-style-type: none"> • Device labelling in German • Insurance required to be taken out by company conducting business in Germany minimum €500,000 per subject • Hospital may charge for the CI • Devices may not be reimbursed during a CI 	

GREECE

Competent Authority Contact Information	
Contact Person	Mrs. E Vekri
Address	Organization for Medicines, 284 Mesogion Ave 155 62 Holargos-Athens, Greece
Telephone	+ 30 21 06 50 74 61
Fax	+ 30 21 06 50 74 6
Email	ktnast@eof.gr
Website	www.eof.gr
Applicable Regulations	
AIMDD	90/385/EC as transposed into national law
MDD	93/42/EC as transposed into national law
IVDD	98/79/EC as transposed into national law
Other regs/guidelines	None Known
CA Notification Requirements	
<ul style="list-style-type: none"> • Notification required for all clinical investigations • 60 day waiting period obligatory • €6010.27 charged for notification • Language can be English 	
Ethics Committee Information	
<ul style="list-style-type: none"> • Cost varies between committees • Submit to committee attached to hospital where study is to be conducted • Documents in Greek 	
Comments/Practical Experience	
<ul style="list-style-type: none"> • Device labelling in Greek • Insurance required by law • Hospital may charge for the study • Devices for clinical investigation not reimbursed 	

HUNGARY

Competent Authority Contact Information	
Contact Person	Dr Peter Bunyitai
Address	Authority for Medical Devices, Akademia, 3 Budapest V, H-1054 Hungary
Telephone	+36 1 302 5060
Fax	+36 1 269 1255
Email	p.bunyitai@eum.hu
Website	www.eum.hu
Applicable Regulations	
AIMDD	90/385/EC as transposed into national law
MDD	93/42/EC as transposed into national law
IVDD	98/79/EC as transposed into national law
Other regs/guidelines	
CA Notification Requirements	
<ul style="list-style-type: none"> • Notification required for all clinical investigations • Ethics committee approval required before submission to CA • Documents to be submitted include, CIP, CRF, IB, consent docs, Ministry of Health Ethics Committee approval, CIP summary and all labels. Most Investigational documents can be in English except; patient documents, packaging and IFU which must be in Hungarian • 60 day waiting period although approval usually given within 30 days • Fees are not charged for notification • Standard notification form available in Hungarian only 	
Ethics Committee Information	
<ul style="list-style-type: none"> • Ethical approval required from Ethics Committee for Medical Devices of the Medical Research Council of the Ministry of Health before CA submission • Once CA have granted approval, ethical approval then required from each hospitals' EC • Currently no fees are charged by ethics committees • Most documents can be in English (except consent docs and patient specific docs which must be in Hungarian) 	
Comments/Practical Experience	
<ul style="list-style-type: none"> • Device labelling in Hungarian • Ethics committees plan to start charging in the near future • Insurance required • Hospital may charge for the study 	

ICELAND

Competent Authority Contact Information	
Contact Person	Vilborg Ingólfssdóttir
Address	Directorate of Health, Austurströnd 5, IS-170 Seltjarnes, Iceland
Telephone	+ 354 510 1900
Fax	+ 354 510 1919
Email	vilborg@landlaeknir.is
Website	www.landlaeknir.is
Applicable Regulations	
AIMDD	90/385/EC as transposed into national law
MDD	93/42/EC as transposed into national law
IVDD	98/79/EC as transposed into national law
Other regs/guidelines	Reg no. 552/1999 on scientific research in the health sector
CA Notification Requirements	
<ul style="list-style-type: none"> • Notification required for all clinical investigations • Ethics Committee approval required before submission to CA • Documents to be submitted include, CIP, CRF, IB, EC approval, consent docs, insurance, investigators qualifications and statement of conformity with the directive • 60 day waiting period obligatory • Fees are charged for notification • Standard notification form available • Language English acceptable 	
Ethics Committee Information	
<ul style="list-style-type: none"> • Ethics Committee Approval required before submission to CA • Cost varies • Submit to committee attached to hospital where study is to be conducted • Most documents can be in English (except consent docs and patient specific docs) 	
Comments/Practical Experience	
<ul style="list-style-type: none"> • Insurance recommended • Hospital may charge for the study • Devices for clinical investigation must not be sold to sites 	

IRELAND

Competent Authority Contact Information	
Contact Person	Mrs. Ann O'Connor
Address	Irish Medicines Board, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland
Telephone	+ 353 1 6764971
Fax	+ 353 1 6767836
Email	medicaldevices@imb.ie
Website	www.imb.ie
Applicable Regulations	
AIMDD	90/385/EC as transposed into national law
MDD	93/42/EC as transposed into national law
IVDD	98/79/EC as transposed into national law
Other regs/guidelines	None Known
CA Notification Requirements	
<ul style="list-style-type: none"> • Notification required for all clinical investigations • 60 day waiting period obligatory • Fees are charged for notification AIMD, Class III & IIb €2539 & Class IIa & I €1270. An amendment costs €1000. • Standard notification form available on website along with guidance notes 	
Ethics Committee Information	
<ul style="list-style-type: none"> • 50 ECs across Ireland 33 attached to hospitals or healthboards others universities or other institutions • Cost of submission varies • Submit to committee attached to hospital where study is to be conducted 	
Comments/Practical Experience	
<ul style="list-style-type: none"> • Insurance necessary along with Indemnity for institutions conducting research • Hospital may charge for the study • Devices for clinical investigation may not be reimbursed 	

ITALY

Competent Authority Contact Information	
Contact Person	Dott.SSA Marcella Marletta
Address	Ministry of health Dipartimento dell'innovazione Direzione Generale dei Farmaci e Dispositivi Medici Ufficio Dispositivi Medici Piazzale dell'Industria 20 0144 Roma, Italy
Telephone	+ 39 06 59942423
Fax	+ 39 06 59942111
Email	m.marletta@sanita.it
Website	www.sanita.it/dispmed
Applicable Regulations	
AIMDD	90/385/EC as transposed into national law
MDD	93/42/EC as transposed into national law
IVDD	98/79/EC as transposed into national law
Other regs/guidelines	May need to adhere to Italy's GCP laws
CA Notification Requirements	
<ul style="list-style-type: none"> • Notification required for all clinical investigations • Documents to be submitted include, CIP, CRF, IB, EC approval, consent docs, insurance, investigators qualifications, statement of conformity with directive • 60 day waiting period obligatory • Fees are charged for notification • Language Italian or English 	
Ethics Committee Information	
<ul style="list-style-type: none"> • Documents normally need to be in Italian • Fees Vary • Submit to committee attached to hospital where study is to be conducted 	
Comments/Practical Experience	
<ul style="list-style-type: none"> • Device labelling in Italian • Insurance required by law • Hospital may charge fees • Reimbursement depends on hospital and insurer • CIs should be done in public hospitals only • May need to follow Italy's GCP laws 	

LATVIA

Competent Authority Contact Information	
Contact Person	Iveta Gavare, Alnis Dambergs
Address	Health Statistics & Medical Technologies State Agency, Dunties Street 12/22, Riga, LV-1005, Latvia
Telephone	+37 1 7387653
Fax	+37 1 7501591
Email	iveta@vsmta.lv , alnis@vsmta.lv
Website	www.vsmta.lv
Applicable Regulations	
AIMDD	90/385/EC due to be transposed before Dec 2005
MDD	93/42/EC due to be transposed before Dec 2005
IVDD	98/79/EC due to be transposed before Dec 2005
Other regs/guidelines	Currently MDD, IVDD, AIDD have not been transposed into national law. National laws being used in the interim.
CA Notification Requirements	
<ul style="list-style-type: none"> • Notification required for all clinical investigations • Ethics committee approval required before submission to CA • Documents to be submitted include, CIP, CRF, IB, EC approval, consent docs, insurance, details of all people involved in the Clinical Investigation including CROs, statisticians, all Clinical Investigators within Latvia • Fees are charged for notification • Submission to CA may be in Latvian, Russian or English. All patient docs must be in Latvian and Russian. 	
Ethics Committee Information	
<ul style="list-style-type: none"> • Ethics committee approval required before submission to CA • Approval from National Biomedical Ethics Committee must be sought first then from the ethics committee at the Accredited Hospital where the research will be undertaken. • Documents normally need to be in Latvian or Russian. English is not usually accepted by ethics committees • Fees vary • Documents submitted to Ethics Committees are the same as the docs submitted to the CA 	
Comments/Practical Experience	
<ul style="list-style-type: none"> • Device labelling in Latvian and Russian • Insurance is advisable but not a requirement • Hospital may charge fees • Reimbursement depends on hospital and insurer • CIs should be done in accredited hospitals only 	

LITHUANIA

Competent Authority Contact Information	
Contact Person	Ms. Angele Kazlauskiene
Address	State Health Care Accreditation Agency, Ž.Liauksmينو str. 5, LT-01101 Vilnius, Lithuania
Telephone	+(370) 5 2615147
Fax	+(370) 5 2127310
Email	angelekaz@takas.lt
Website	www.takas.lt
Applicable Regulations	
AIMDD	90/385/EC not currently transposed into national law
MDD	93/42/EC not currently transposed into national law
IVDD	98/79/EC not currently transposed into national law
Other regs/guidelines	Law on Ethics of Biomedical Research of the Republic of Lithuania
CA Notification Requirements	
<ul style="list-style-type: none"> • Official approval for all Clinical Investigations will be given by the Lithuanian Bioethics Committee (LBEK), the CA will give recommendations and/or approval to the LBEK but will not officially give approval to the Sponsor • Notification required for all clinical investigations • Ethics committee approval required before submission to CA • Documents to be submitted include, CIP, CRF, IB, consent docs, insurance, details of all people involved in the Clinical Investigation including CROs, statisticians, all Clinical Investigators within Lithuania • Sponsor/Coordinating Clinical Investigator may be required to give a presentation in person • Fees are charged for notification • Submission to CA may be in Lithuanian, Russian or English 	
Ethics Committee Information	
<ul style="list-style-type: none"> • Approval from Lithuanian Bioethics Committee (LBEK) must be sought before submission to CA, LBEK will inform all Local Ethics committees of its decision and pass all documents on to them for review of local issues. • Local Ethics committees' decision takes 15 days and can be overridden by the LBEK • Ethics committee approval required before submission to CA • Documents must all be in Lithuanian or Russian • An estimate of fees will be given upon request as these differ for each submission due to LBEK charging to cover all expenses • Documents submitted to Ethics Committees include CIP, Patient docs, copy of all forms completed and sent to CA, application form for ethical review, Sponsor's personal ethical assessment and the CVs of all Clinical Investigators with details of Lithuanian medical licences for each Clinical Investigator • LBEK aims to give a decision within 45 days 	
Comments/Practical Experience	
<ul style="list-style-type: none"> • Device labelling in Lithuanian or Russian • Insurance required by law • Hospital may charge fees 	

LUXEMBOURG

Competent Authority Contact Information	
Contact Person	Dr. Gérard Scharll
Address	Ministère de la Santé Allée Marconi-Villa Louvigny L-2120 Luxembourg
Telephone	+ 352 478 56 34
Fax	+ 352 262 03 296
Email	Gerard.scharll@ms.etat.lu
Website	www.etat.lu/MS/
Applicable Regulations	
AIMDD	90/385/EC as transposed into national law
MDD	93/42/EC as transposed into national law
IVDD	98/79/EC as transposed into national law
Other regs/guidelines	Information and packaging of the CA application must be exactly as requested or the entire pack will be returned to the applicant
CA Notification Requirements	
<ul style="list-style-type: none"> • Notification required for all clinical investigations • Ethics committee approval required before submission to CA • Documents to be submitted include; CIP (+ summary in French or German), consent docs, IB, IFU in French/German, CRF, EC approval, CV of all Investigators in Luxembourg and a statement of conformity with the directive • 60 day waiting period obligatory for class IIa, IIb, III and AIMD • No obligatory waiting period for class I devices • €247.39 charged for notification, • Language German, French or Letzeburgish preferred but will accept English 	
Ethics Committee Information	
<ul style="list-style-type: none"> • Ethics Committee approval required before submission to CA • Fees vary between committees • Submit to committee attached to hospital where study is to be conducted • Most documents can be in English (except consent docs and patient specific docs which must be in German, French, Letzeburgish. The language chosen will depend on the region.) 	
Comments/Practical Experience	
<ul style="list-style-type: none"> • Device labelling in French, German, Letzeburgish • Insurance required • Hospital may charge for the study • Devices for clinical investigation will be expected to be free of charge 	

NETHERLANDS

Competent Authority Contact Information	
Contact Person	Mrs. Sabina Hoekstra-van den Bosch, Pharm. D. Mr. Jos Kraus Ms L M de Vries
Address	Legislation: Ministry of Health Welfare and Sport P.O. Box 20350 2500 EJ The Hague, The Netherlands. Law Enforcement: Healthcare Inspectorate, Parnassusplein 5, 2511 VX The Hague, The Netherlands
Telephone	+ 31 70 3405 368, + 31 70 3406 150, +31 70 3407 118
Fax	+ 31 70 3407 187, + 31 70 3407 159
Email	Sl.hoekstra@minvws.nl , medtech.higz@igz.nl
Website	www.minvws.nl , www.igz.nl
Applicable Regulations	
AIMDD	90/385/EC as transposed into national law
MDD	93/42/EC as transposed into national law
IVDD	98/79/EC as transposed into national law
Other regs/guidelines	May need to adhere to GCP
CA Notification Requirements	
<ul style="list-style-type: none"> • Notification required for all clinical investigations • Accredited Ethics Committee approval required before CA submission • Documents to submit include CIP, CRF, consent docs and IB • Specific guidance issued by the CA outlining the procedure for clinical investigations • No 60 day obligatory waiting period • No fees • No application form • Language can be English 	
Ethics Committee Information	
<ul style="list-style-type: none"> • Ethics committee approval required before submission to CA • Submit to one accredited EC (aEC) • aEC will submit docs to the Local Hospital Board of Directors at each investigation site within the Netherlands for approval. • Each Hospital Board of Directors independently reviews the documents and forwards them to the Local Ethics Committee for final review of local ethical issues. • Cost varies between committees • Most documents can be in English (except consent docs and patient specific docs) 	
Comments/Practical Experience	
<ul style="list-style-type: none"> • Device labelling in Dutch and requires approval from CA • Insurance requirements very specific and required by law • Hospital may charge for the study • Investigational devices must not be sold to sites 	

NORWAY

Competent Authority Contact Information	
Contact Person	T Ringerike
Address	Directorate for Health and Social Affairs, PO Box 7000, St Olavs plass, N-0130, Oslo
Telephone	+47 24 16 30 00
Fax	+47 24 16 30 01
Email	Tove.Ringerike@legemiddelverket.no
Website	www.shdir.no
Applicable Regulations	
AIMDD	90/385/EC as transposed into national law
MDD	93/42/EC as transposed into national law
IVDD	98/79/EC as transposed into national law
Other regs/guidelines	
CA Notification Requirements	
<ul style="list-style-type: none"> • Notification required for all clinical investigations • Ethical approval required before submission to CA • Documents to be submitted include, CIP, CRF, IB, Ethical approval and consent docs • 60 day waiting period obligatory • Fees are charged for notification 5000NOK • Standard notification form available in Norwegian • Language can be English • All documents can be in English except patient docs and IFU 	
Ethics Committee Information	
<ul style="list-style-type: none"> • Ethical approval required from one of the five regional ethics committees where the Clinical Investigation is due to occur. If the Clinical Investigation has more than one investigational site within Norway then only need to apply to Chief Investigator's regional ethics committee • Ethical approval required before submission to CA • Currently no fees are charged by ethics committees • Ethical opinion usually given within 30 days • Most documents can be in English (except consent docs and patient specific docs which must be in Norwegian) • All documents must be provided in 12 copies before being viewed by the committee 	
Comments/Practical Experience	
<ul style="list-style-type: none"> • Device labelling in Norwegian • Insurance required • Hospital may charge for the study • Investigational devices usually expected to be provided free of charge to hospitals 	

POLAND

Competent Authority Contact Information	
Contact Person	Ewa Dytowska
Address	The Office for Registration of Medical Products, Medical Devices and Biomedical Products, 41 Z ¹ bowska Str, 03-736
Telephone	+48 (22) 492 11 00
Fax	+48 (22) 492 11 09
Email	Ewa.dytowska@urpl.gov.pl
Website	www.urpl.gov.pl , www.mz.gov.pl
Applicable Regulations	
AIMDD	90/385/EC due to be transposed into national law
MDD	93/42/EC due to be transposed into national law
IVDD	98/79/EC due to be transposed into national law
Other regs/guidelines	Currently MDD, IVDD, AIDD have not been transposed into national law. National laws being used in the interim of which there are three: The Act of Medical Devices April 2004, Ordinance of the Minister of Health concerning Clinical Investigations April 2004 and The Act of Medical Profession 1999
CA Notification Requirements	
<ul style="list-style-type: none"> • Notification required for all clinical investigations • Ethics committee approval required before submission to CA • Documents to be submitted include, CIP, CRF, IB, EC approval, consent docs, insurance, declaration of conformity and details of all Clinical Investigators within Poland • Fees are charged for notification depending on the Class of device 1000-5000 PLN • Submission to CA may be in Polish or English however CIP, all patient docs and manufacturers declaration of conformity must be in Polish • Application form available online in Polish 	
Ethics Committee Information	
<ul style="list-style-type: none"> • For Multi-Centre Clinical Investigations only one ethical opinion is required from the co-ordinating centre within Poland • Approval from an ethics committee must be obtained before submission to the CA • Fees Vary between committees as there is no regulation to how much a committee may charge for approval, most charge around €2000 • Documents submitted to Ethics Committees are CIP, insurance and patient docs all of which must be in Polish • No forms are available, all information required should be in the Investigational Docs 	
Comments/Practical Experience	
<ul style="list-style-type: none"> • Device labelling in Polish and Russian (where deemed necessary) • Insurance is required by law • Hospital may charge fees 	

PORTUGAL

Competent Authority Contact Information	
Contact Person	Judite Neves Pharm D – Head of Deptment of Medical Devices
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Telephone	+ 351 21 798 72 90
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Email	daps@infarmed.pt , mraquel.alves@infarmed.pt
Website	www.infarmed.pt
Applicable Regulations	
AIMDD	90/385/EC as transposed into national law
MDD	93/42/EC as transposed into national law
IVDD	98/79/EC as transposed into national law
Other regs/guidelines	None Known
CA Notification Requirements	
<ul style="list-style-type: none"> • Notification required for all clinical investigations • Ethics committee approval required before submission to CA • 60 day waiting period obligatory • Fees are charged for notification • Guidance notes for notification available form website www.infarmed.pt along with forms for completion • Language Portuguese, Spanish 	
Ethics Committee Information	
<ul style="list-style-type: none"> • Cost may vary between committees • Ethics committee approval required before submission to the CA • Submit to committee attached to hospital where study is to be conducted • Most documents to be in portuguese 	
Comments/Practical Experience	
<ul style="list-style-type: none"> • Device labelling in Portuguese • Insurance required • Hospital may charge for the study • Hospital or head of department needs to give approval for the study 	

SPAIN

Competent Authority Contact Information	
Contact Person	Mrs. C Grau, Mrs Maria Teresa de Martín y Martinez
Address	Ministerio Sanida y Consumo Agencia Española de Medicamentos y Productos Sanitarios Paseo del Prado 18-20 28024 Madrid, Spain
Telephone	+ 34 91 596 43 47, +34 91 822 52 70
Fax	+ 34 91 596 44 00, +34 91 822 52 89
Email	cgrau@agemed.es ,
Website	www.msc.es & www.agemed.es
Applicable Regulations	
AIMDD	90/385/EC as transposed into national law
MDD	93/42/EC as transposed into national law
IVDD	98/79/EC as transposed into national law
Other regs/guidelines	A separate decree exists and is available from website
CA Notification Requirements	
<ul style="list-style-type: none"> • Notification required for all clinical investigations • Documents to be submitted include, CIP, CRF, IB, EC approval, consent docs, insurance, investigators qualifications, statement of conformity with directive and monitor details • 60 day waiting period obligatory • Fees are charged for notification • Standard notification form with list of items to send • Language Spanish 	
Ethics Committee Information	
<ul style="list-style-type: none"> • Documentation to submit includes, CIP & summary, consent documents in Spanish, CE certificate for CE marked products, CRFs, IFU, insurance policy a list is available from most ECs • Cost varies between committees • Submit to committee attached to hospital where study is to be conducted • Most documents to be in Spanish 	
Comments/Practical Experience	
<ul style="list-style-type: none"> • Device labelling in Spanish • Insurance required by law • Hospital may charge for the study and will need to give approval for the study • Devices for clinical investigation are to be provided free of charge to hospitals 	

SWEDEN

Competent Authority Contact Information	
Contact Person	AIMDD- Dr. Lennart Philipson, MDD & IVDD-Mr. Lars Johansson
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Telephone	+ 46 18 17 46 00
Fax	+ 46 18 50 31 15
Email	Lennart.philipson@mpa.se , lars.johansson@mpa.se
Website	www.mpa.se www.codex.vr.se
Applicable Regulations	
AIMDD	90/385/EC as transposed into national law
MDD	93/42/EC as transposed into national law
IVDD	98/79/EC as transposed into national law
Other regs/guidelines	Must comply with ISO 14155 for CIs
CA Notification Requirements	
<ul style="list-style-type: none"> • Notification required for all clinical investigations • Ethics committee approval required before submission to CA • Documents to be submitted include, CIP, CRF, IB, EC approval, consent docs, insurance, investigators qualifications, statement of conformity with directive 60 day waiting period obligatory • Fees are charged for notification SEK 20,000 • Standard notification form available in English • Language can be English 	
Ethics Committee Information	
<ul style="list-style-type: none"> • Ethics committee approval required before submission to CA • Cost varies between committees from SEK5000 to SEK16000 • Submit to Regional Ethics Committees where the clinical investigation is to take place • Ethical Approval usually takes 60 days • Central Ethics Committee is only for appeals against Regional Ethics Committee decisions and to assist Regional Ethics Committees if they are unable to reach a unanimous decision. • Most documents can be in English (except consent docs and patient specific docs) 	
Comments/Practical Experience	
<ul style="list-style-type: none"> • Device labelling in Swedish • Insurance required • Hospital may charge for the study • No reimbursement for devices for clinical investigation 	

SWITZERLAND

Competent Authority Contact Information	
Contact Person	Dr Isabel Scuntaro
Address	Swissmedic, Medical Devices Division, Hallestrasse 7, CH-3000, Bern 9
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Fax	+ 41 (0) 31 322 76 46
Email	Isabel.scuntaro@swissmedic.ch
Website	www.swissmedic.ch
Applicable Regulations	
AIMDD	90/385/EC as transposed into national law
MDD	93/42/EC as transposed into national law
IVDD	98/79/EC as transposed into national law
Other regs/guidelines	
CA Notification Requirements	
<ul style="list-style-type: none"> • Notification required for all clinical investigations • Ethics committee approval required before submission to CA • Documents to be submitted include, CIP, CRF, IB, EC approval, consent docs, insurance, list of all Investigators, CV of Co-ordinating Clinical Investigator • 60 day waiting period obligatory • Fees are charged for notification CHF-1000 • Standard notification form available in English • Investigational documents can be in English with the exception of the patient docs which should be in either French, German or Italian 	
Ethics Committee Information	
<ul style="list-style-type: none"> • Cost varies between committees • Submit to committee attached to hospital where study is to be conducted • Documents preferred in French, German or Italian. English may be considered depending on the committee • Ethic approval required before submission to CA 	
Comments/Practical Experience	
<ul style="list-style-type: none"> • Insurance required • Hospital may charge for the study 	

UNITED KINGDOM

Competent Authority Contact Information	
Contact Person	Dr. Susanne Ludgate
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Fax	+ 44 (0)2079728111
Email	Susanne.ludgate@mhra.gov.uk
Website	www.mhra.gov.uk
Applicable Regulations	
AIMDD	90/385/EC as transposed into national law
MDD	93/42/EC as transposed into national law
IVDD	98/79/EC as transposed into national law
Other regs/guidelines	Clinical Investigations should be conducted to ISO14155
CA Notification Requirements	
<ul style="list-style-type: none"> • Notification required for all clinical investigations • Documents to be submitted include, CIP, CRF, IB, EC approval, consent docs, insurance, investigators qualifications, statement of conformity with directive full list available in guidance document downloadable from website www.mhra.gov.uk • 60 day waiting period obligatory • Fees are charged for notification £2,200 for Class I-IIb (other than long term implantable) £3000 for Class IIb-III long term invasive devices • Standard notification form available on website PCA I and PCA II • EC opinion can be conducted at same time but outcome to be notified to MHRA before investigation can commence 	
Ethics Committee Information	
<ul style="list-style-type: none"> • All studies with more than one site in UK to go through COREC (Central Office Research Ethics Committees) • No fees • Submit to committee attached to hospital where study is to be conducted for single sites • www.corec.org.uk for all information on ECs in UK 	
Comments/Practical Experience	
<ul style="list-style-type: none"> • Pre submission meeting recommended with MHRA • Insurance required for ECs • Hospital may charge for the study require R&D approval at most centres • Devices can be charged for at most centres 	