Medical Devices - ITALY

Competent authority

Contact Details	**Contact Name 1** Ministry of Health/ Ministero della Salute - Direzione Generale dei Dispositive Medici, del servizio Farmaceutico e della Sicurezza delle Cure (DGDFSC) **Contact Name 2** Ufficio 06: Sperimentazione clinica dei dispositive medici éx DGFDM **Phone** +39 0659943199 - 3392 **Email General** Segr.DGFDM@sanita.it **Email Department** dgfdm@postacert.sanita.it **Address** Vialle Giorgio Ribotta, 5 **ZIP/City** 00144 Rome **Country** Italy (IT) **Web address** http://www.salute.gov.it **Additional Information** NB: No local CA.
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 MD Class III Other high-risk devices (Class IIa or IIb implantable and long-term invasive MDs) **CA - Registration/ notification without approval required for** Observational MD investigations MD CE-marked, use within label MD CE-marked, use within label + IMP MD Class I MD Class IIa MD Class IIb **CA - Submission required to** –

	Applicable national legal framework/ Reference Section 14.8 Legislative Decree/ Decreto lgs. n. 46/97, as amended by Legislative Decree n. 37/2010 Section 2.2 Legislative Decree/ Decreto lgs. n. 46/97, as amended by Legislative Decree n. 37/2010 **Submission to CA and EC to be performed in the following order** –
Submission of Application	**Responsible for study submission** Sponsor Legal representative domiciled in the EU/EEA **Entitled to study submission** – **Prerequisites for submission** – **Guidance on submission of application** Detailed guidance on the Notification procedure for non-CE- marked (pre market) MD to the CA as well as for CE-marked MD (post market) is available on the Ministry of Health's website.
Submission Format	**Format option(s)** post (in paper form with CD-ROM) or electronically (via e-mail to the following address: dgfdm@postacert.sanita.it) **Preferred format** – **Standard application form available** Yes **Standard application form** The online form is available on the Ministry of Health website for Notification of clinical trials: (1) with CE-marked MD (post market): Home > Ministro e Ministero > Moduli e servizi online > Comunicazione di avvio indagini cliniche post market > Moduli. (2) with non-CE-marked MD (pre market): Home > Ministro e Ministero > Moduli e servizi online > Notifica di indagini cliniche svolte con dispositivi medici non recanti la marcatura CE (pre market) > Moduli.
Language of Submission	**Language(s) of application** Italian **Preferred language of application** – **English accepted** Yes **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** Submission fee for authorization requests (where applicable): EURO 2160,45 .-
Timelines Authorisation	**General timespan (max nr days)** 60 **Mode of approval (General)** Tacit (Silent) **Clock-stop possible if complementary information requested** Yes **Timespan counted from** – **Additional Information** If the study is a post-market trial (CE-marked use within label, class I, IIa and IIb) only a notification of the start to CA is required (no timelines apply).
Amendments/ Substantial Amendments (SA)	**Notification mandatory for** – **Authorisation mandatory for** Investigations of devices used outside label or without CE mark **Responsible for submission of SA** Sponsor **Timeline for approval of SA (max nr days)** – **Additional Information** If the device is used according to CE mark only a notification to EC is required!
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) **SUSAR being life-thereatening or leading to death must be reported** – **All other SUSARs** – **SAE /SADE must be reported** According to timelines specified in MEDDEV 2.7/3 December 2010 **National standard reporting form available** European standard SAE reporting form MEDDEV 2.7/3 to be used

	Standard Reporting Form Pre-market MD: Reporting of SAE/Incidents should be done according to the templates provided in Appendix (reporting form) of Meddev 2.7/3. **Reporting format - Options** – **Preferred format** – **Provision of Annual safety report mandatory** No **Annual safety report shall be provided by sponsor to** Not required, but the CA could require it in case of device without CE mark or used off-label.Not **Guidance on AE reporting procedure available** Yes **Guidance on AE reporting procedure** Post market MDs (CE-marked use within label): Guidelines MEDDEV 2.12-2, rev.2 Jan 12. Reporting via the Medical Device Vigilance System Pre market MDs: MEDDEV 2.7/3 December 2010 (serious adverse reporting) **National legal framework in place** Yes **Applicable national legal framework/ Reference** The international standard ISO14155:2011 (Clinical investigation of medical devices for human subjects – Good Clinical Practice) applies to all clinical investigations of MD. **Additional Information** Combination studies (MD+MP): Reporting obligations follow the requirements for IMP studies. **Investigator shall report SAE to** – **Reporting timeline** –
End of Trial	**End of trial declaration mandatory for** All clinical trials requiring notification to CA (without approval process) All clinical investigations requiring authorisation by CA **Responsible for End of trial declaration** Sponsor **Regular Termination - Declaration timespan (max nr days)** Not specified **Timespan counted from** – **Early/premature Termination - Declaration timespan (max nr days)** Not specified

Additional Information & Specifics	**Additional Information** Accreditation process for research centres: The Italian Ministry of Health issued a decree on the suitability of investigation sites conducting clinical studies on medical devices, aiming at strengthening the overall safety of patients in Italy. The Ministerial Decree 12 March 2013 upgrades and puts order in the list of Italian sites where clinical investigations involving medical devices not bearing the CE mark can be performed, introducing further types of settings, not previously contemplated under the law.

Ethics committee

Contact Details	**Contact Name 1** Local Ethics Committee **Contact Name 2** There are 84 certified ECs in Italy. **Web address** https://www.agenziafarmaco.gov.it/ricclin/en/node/26 **Additional Information** The complete list of certified ECs available on AIFA website. There is no central EC.
Ethical Review – General	**Submission for Ethical review mandatory for** All clinical investigations of MD **Submission to CA and EC to be performed in the following order** In parallel **Regulatory and ethics bodies involved in approval process** –
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** Local EC **Additional Information** The clinical trial must be submitted to the reference EC of the health facility where the trial is conducted.
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** All local ECs of participating sites **Submission of application required to** All local ECs of participating sites **Additional Information** Submission to all reference ECs of the participating clinical sites is required.
Submission of Application	**Responsible for study submission** Sponsor **Entitled to study submission** – **Prerequisites for submission / approval** –

	Additional Information Sponsor from outside Italy can submit an application for trial evalution to CA and EC
Submission Format	**Format option(s)** Paper hardcopy **Preferred format** – **Standard application form available** No
Language of Submission	**Language(s) of application** Italian **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** € 2.000,00 – to 4000,00 (for commercial trials)
Timelines Ethical Review	**General timespan for single-centre studies (max nr days)** No timeline specified in national law **General timespan for multi-centre studies (max nr days)** – **External expert advice required: Timespan (max nr days)** – **Timespan counted from** – **Additional Information** Submission deadline: before start-up
Amendments/ Substantial Amendments (SA)	**Ethical review mandatory for** Any substantial amendments **Responsible for notification of SA** Sponsor **Timeline Ethical review of SA (max nr days)** –

	Additional Information Studies with CE-marked MD (use within label) require notification to EC only (not to CA!).
Safety Reporting	**Reportable AEs** SAE (Serious Adverse Event) SADE (Serious Adverse Device Effect) **Investigator shall report SAE to** Sponsor **Reporting timeline** – **Responsible for AE reporting to relevant EC(s)** Sponsor Principal Investigator **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** – **Guidance on AE reporting procedure** According to MEDDEV 2.7/3 December 2010 (Clinical Investigations: serious adverse reporting (pre CE- mark)) **Additional Information** SAE/SADE must be reported to EC(s) for interventional clinical investigations on MD (MD CE-marked, within or outside label; MD without label, respective combination studies).
End of Trial	**End of trial Declaration mandatory** Yes **Responsible for End of trial Declaration** Sponsor **Regular Termination - Declaration timespan (max nr days)** Not specified **Timespan counted from** – **Early/premature Termination - Declaration timespan (max nr days)** Not specified

Additional Information

The sponsor shall declare the end of the trial (preliminary or scheduled) to the CA and the ECs.

Study specific Requirements

Sponsor	**Sponsorship mandatory** Yes **Sponsorship mandatory - Additional information** Sponsor is mandatory for interventional and observational investigations of MD. No formal definition of Sponsor for registries. **Co-Sponsor - Definition available in national law** No **Co-sponsorship allowed** No **Legal representative based in the EU/EEA is mandatory where Sponsor is located outside EU/EEA:** Yes
Study Participants - Informed Consent (IC)	**Standard IC form (ICF) available** Not specified **IC is regulated by law** Yes **Informed Consent - Definition/ Requirements** Same rules as for medicinal products apply. Informed Consent is specified in Section 2-5 of Legislative Decree n. 211: It is the decision to take part in a clinical trial which must be written, dated and signed, taken freely after being duly informed o f its nature, significance, implication, risks and right to revoke any time without detriment to the subject. If the person concerned is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases. When the person is not capable of giving consent, the informed consent can be obtained by his or her legal representative if the subject's presumed will is represented. For genetic or genotype/phenotype studies a specific informed consent is required and the aim of the study should be stated when the informed consent is obtained. If the stored material is later used for other purpose than the originally stated ones, a new informed consent should be obtained again from the participants.
Study Participants - Vulnerable Population	**Minors / Children - Studies allowed** Yes Special provisions apply **Specific provision** Same rules as for IMP trials **Legal framework/Reference (Minors/Children)** Section 4 of Legislative Decree n. 211 **Incapacitated persons - Studies allowed** Yes Special provisions apply

Specific provisions

Same rules as for IMP trials

Legal framework / Reference (Incapacitated persons)

Section 5 of Legislative Decree n. 211.

Emergency situations - Studies allowed

No national legal framework available

Specific provisions

Same rules as for IMP trials:
The involvement of subjects in emergency situations in a clinical trial is not explicitly mentioned in Italian law (see sections on vulnerable persons in Legislative Decree n. 211).

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

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Pregnant or breastfeeding women - Studies allowed

No national legal framework available

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

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Data Protection Authority/ Agency - Contact Details

Italian Data Protection Authority DPA - Garante per la Protezione dei Dati Personali

E-Mail

rp@gpdp.it

Address

Piazza di Monte Citorio, 121

ZIP/City

00186 Rome

Country

Italy (IT)

Additional Information

The rights of the subject to physical and mental integrity, to privacy ant to the protection to the personal date are regulated and safeguarded by the Data Protection Code - Legislative Decree no. 196/2003, superseding the Data Protection Act 1996 (Statute no. 675 of 31 Dec 1996).

	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** Patients/Volunteers Study participants **Responsible for covering insurance** Sponsor **Insurance fee: A minimum coverage sum is defined** Yes **Minimum coverage sum** Not specified
Quality Assurance/ Quality Control (QA/QC)	**Monitoring** Optional **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** Ministerio della Salute - Section: Normativa **Additional Information** The national legislation related to medical device studies is somewhat less specific than the legislation concerning IMP trials.
Investigations on Medical Devices	**Applicable national regulations** Transposition of EU Directives on MD Other **Transposition of Directive 90/385/EEC** Legislative Decree n. 507/92 (Decreto lgs. n. 507/92) on Non active implantable medical devices, as amended by Legislative Decree n. 37/2010 (Decreto lgs. N.37/2010) implementing Directive 2007/47/EC. **Transposition of Directive 93/42/EEC** Legislative Decree n. 46/97 (Decreto lgs. n. 46/97) on medical devices, as amended by Legislative Decree n. 37/2010 (Decreto lgs. N.37/2010) implementing Directive 2007/47/EC. **Transposition of Directive 98/79/EC** Legislative Decree n. 332/2000 (Decreto lgs. n. 332/2000) on in vitro diagnostic medical devices (implementing Directive 98/79/EC), as amended by Legislative Decree n. 37/2010 (Decreto lgs. N.37/2010) implementing Directive 2007/47/EC.

	Other applicable regulations / implementing provisions (Acts, laws, decrees, ordinances, circulars, etc) Ministerial Decree, 2 Aug 2005. Official Journal n. 210 September 9, 2005 (Decreto del Ministero della Salute, 2 agosto 2005: Modalita' di presentazione della documentazione per notifica di indagine clinica con dispositivi medici) **Additional Information** In addition, internationally accepted documents such as the Declaration of Helsinki and ISO 14155:2011 apply to all categories of clinical investigations of MD. European regulatory requirements European Directive (2001/20/EC) additionally apply to combination studies.
Radiation & Radiotherapy	**Use of radiation or radioactive compounds - Specific requirements** Yes **Applicable legal framework** For the use of devices emitting radiation: Legislative Decree 17 March 1995 nr 230 modified by - Legislative Decree 26 May 2000 n. 187, - Legislative Decree 26 May 2000 nr. 241, and - Legislative Decree 9 May 2001 nr. 257
Blood & Tissue Samples	**Specific requirements** Yes **Applicable legal framework** Regulated by rules of the Ministry of Health July 20, 1996 n.16.
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 Code - Legislative Decree no. 196/2003