Medical Device	Italy
Competent Authority	
Contact Details	
Contact name 1	Ministry of Health - Direzione Generale dei Dispositivi Medici e del servizio Farmaceutico (DGDMF)
Contact name 2	Office 06: Sperimentazione clinica dei dispositivi medici
Contact name 3	Director Pietro Calamea
Phone	+39 06 59942669
Fax	N/A
Email General	p.calamea@sanita.it
Email Department	N/A
Address	Viale Giorgio Ribotta, 5
ZIP/City	00144 Rome
Country	Italy
Web address	https://www.salute.gov.it/portale/dispositiviMedici/menuContenutoDispositiviMedici.jsp?lingua=italiano&area=dispositivi-medici&m
Additional information	
Clinical Investigation Authorisation / Registration / Notification	
Regulatory & ethics bodies involved in approval proccess	Ministry of Health Ethics committee(s)
CA - Submission for authorisation mandatory for...	All research projects involving humans
CE-marked MD used within label are exempted from any notification obligation to CA	No
Guidance on submission of application available	Yes
Guidance on submission of application	https://www.salute.gov.it/portale/dispositiviMedici/menuContenutoDispositiviMedici.jsp?lingua=italiano&area=dispositivi-medici&m
National legal framework in place	Yes
Applicable national legal framework/reference	• Medical Device Regulation EU 2017/745 • DL 05/08/2022 n.137 • MoH decree 12/04/2023 • MoH decree 20/03/2023 • DM 26/01/2005 • MoH decree 07/08/2012 • DM 16/01/2019 • Regulation (EU) 2016/679 • MoH decree 06/08/2021
Additional information	N/A
Submission Format	
Online portal	
Standard application form available	Yes

Medical Device	Italy
Standard application form	The online form is available on the Ministry of Health website for Notification of clinical trials: (1) with CE-marked MD (PMCF - Post Market Clinical Follow up): https://www.salute.gov.it/portale/moduliServizi/dettaglioSchedaModuliServizi.jsp?lingua=italiano&label=servizionline&idMat=DM&idAmb=SC&idSrv=POST2&flag=P (2) with non-CE-marked MD (pre market): • for non-invasive classe I/IIa/IIb MD -> https://www.salute.gov.it/portale/moduliServizi/dettaglioSchedaModuliServizi.jsp?lingua=italiano&label=servizionline&idMat=DM&idAmb=SC&idSrv=PRE1&flag=P • for invasive class IIa/IIb MD and for class III MD -> https://www.salute.gov.it/portale/moduliServizi/dettaglioSchedaModuliServizi.jsp?lingua=italiano&label=servizionline&idMat=DM&idAmb=SC&idSrv=PRE2&flag=P
Standard application form - additional information	
Use of standard application form binding	Not applicable
Guidance on submission format available	Yes
Guidance on submission format	
National legal framework in place	Yes
Applicable national legal framework/reference	
Additional information	N/A
Language of Submission	
Language(s) of application	Italian English
English accepted	Yes
Documents mandatory to be in official national language	Not specified
National legal framework in place	N/A
Applicable national legal framework/reference	N/A
Additional information	N/A
Submission Fees	
Fees for trial submission mandatory	Depends on request
Fees	Submission fee for authorization requests: € 2.245,20 (free for PMCF)
Waiver for academic (non-commercial) studies possible	Not specified
Payment requirements (timelines)	Prior to submission of application
Official guidance on required fees available	Yes
Official guidance on required fees	
National legal framework in place	Yes
Applicable national legal framework/reference	• MD 26/01/2005 • MoH decree 07/08/2012 • MD 16/01/2019

Medical Device	Italy
Additional information	
Timelines Autorisation	
General timespan (maw nr days)	60
Mode of approval	Explicit (written) Tacit (Silent) for PMCF
Clock-stop possible if complementary information requested	Yes
National legal framework in place	No
Applicable national legal framework/reference	N/A
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 MoH is required.
Amendments/Substantial Amendments	
Standard notification form	
Timeline for approval of SA (max nr days)	Not specified
Guidance of submission of SA available	N/A
Guidance of submission of SA	N/A
National legal framework in place	N/A
Applicable national legal framework/reference	N/A
Additional information	
Safety Reporting	
Sponsor must declare reportable events to	MoH
Investogator/PI shall separately report any SAE/SADE to CA	Yes
Reportable AEs	AE (Adverse Event) SAE (Serious Adverse Event)
SUSAR being life-threateningor leading to death must be reported	Immediately
All other SUSARs	N/A
SAE/SADE must be reported	According to timelines specified in DM 26/01/2023
National standard reporting form available	Yes
Standard reporting form	Reporting of SAE/Incidents should be done according to the templates provided to this link https://www.salute.gov.it/DispoVigilancePortaleRapportoOperatoreWeb/
Reporting format - options	Electronically
Online safety reporting portal	
Provision of annual safety report mandatory	No
Annual safety report shall be provided by sponsor to	Not specified

Medical Device	Italy
Guidance on AE reporting procedure available	Yes
Guidance on AE reporting procedure	MDCG 2020-10/1 Rev 1 Safety reporting in clinical investigations of medical devices under the Regulation (EU) 2017/745 https://health.ec.europa.eu/system/files/2022-11/md_mdcg_2020-10-1_guidance_safety_reporting_en.pdf
National legal framework in place	Yes
Applicable national legal framework/reference	• DL 05/08/2022 n.137 • Circular on 29/11/2022 (protocol n. 87235) • MD 26/01/2023 • Circular on 06/06/2023 (protocol n.47854)
Additional information	The international standard ISO 14155:2020 (Clinical investigation of medical devices for human subjects - Good clinical practice) applies to all clinical investigations of MD. For more information: https://www.salute.gov.it/portale/dispositiviMedici/dettaglioContenutiDispositiviMedici.jsp?lingua=italiano&id=26&area=dispositivi-medici&menu=vigilanza
End of trial	
End of trial declaration: who, when, what?	Not specified
Responsible for end of trial declaration	Sponsor
Regular termination - declaration of timespan (max nr days)	Not specified
Timespan counted from	Not specified
Early/premature termination - declaration timespan (max nr days)	Not specified
Reasons for early termination shall be clearly declared	Not applicable
Standard declaration form available	N/A
Standard declaration form	N/A
Guidance on end of trial declaration available	N/A
Guidance on end of trial declaration	N/A
National legal framework in place	N/A
Applicable national legal framework/reference	N/A
Additional information	N/A
Additional Information & Specifics	
Additional Information & Specifics	Special authorizations for the use of medical devices non-CE marked: https://www.salute.gov.it/portale/moduliServizi/dettaglioSchedaModuliServizi.jsp?lingua=italiano&menu=tema&label=servizionline&tema=DM&idMat=DM&idAmb=UC&idSrv=A1&flag=P&gruppoTema=ALL
Ethics Committee	
Contact Details	
Contact name 1	The Law no. 3 of 2018 establishes the limit of 40 territorial ethic committees (TECs) and 3 national ECs.
Contact name 2	
Contact name 3	N/A
Phone	N/A
Fax	N/A

Medical Device	Italy
Email General	N/A
Email Department	N/A
Address	N/A
ZIP/City	N/A
Country	Italy
Web address	https://www.aifa.gov.it/en/comitati-etici-nazionali-cen
Additional information	https://www.gazzettaufficiale.it/eli/id/2023/02/07/23A00852/sg
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
Procedural interaction between CA and EC during approval proccess	Yes
Procedural interaction - additional information	The submission to CA is mandatory for phase I, II, III e IV with medicinal products
Additional information	N/A
Single-Centre Studies - Ethical Review	
Ethical approval (favourable opinion) to be obtained from	Local EC
Additional information	art. 6 - Lgs. decree 211/2003
Multi-Centre Studies - Ethical Review	
Ethical approval (favourable option) required form	Local EC connected to the coordinator (coordinating EC)
Submission of application required to	All local ECs of participating sites
Additional information	art. 7 - Lgs. decree 211/2003
Submission of Application	
Responsible for study submission	Sponsor
Entitled to study submission	Sponsor
Prerequisites for submission	Appropriate insurance
Guidance on submission of application available	Yes
Guidance on submission of application	N/A
National legal framework in place	Yes
Applicable national legal framework/reference	N/A
Additional information	https://www.aifa.gov.it/documents/20142/1619588/indirizzo_valutazione_indagini_cliniche_22_08_2022.pdf
Submission Format	
Format option(s)	Email Paper hardcopy
Preferred format	Not specified
Online portal	N/A

Medical Device	Italy
Standard application form available	No
Standard application form	N/A
Standard application form - additional information	Depending on the local EC requirements.
Use of standard application form binding	Yes
Guidance on submission format available	Yes
Guidance on submission format	It depends on the local EC.
National legal framework in place	No
Applicable national legal framework/reference	N/A
Additional information	European Regulation N. 536/2014
Language of Submission	
Language(s) of application	Italian English
Preferred language of application	N/A
English accepted	Yes
Documents mandatory to be in official national language	Not specified
Documents mandatory to be in local language of study site	Not specified
Documents mandatory to be in language of study participant	Not specified
National legal framework in place	N/A
Applicable national legal framework/reference	N/A
Additional information	N/A
Submission Fees	
Fees for ethical review mandatory	Yes
Waiver for academic (non-commercial) studies possible	N/A
Fees for ethical review	€ 4.000,00 – to 7.000,00
Official guidance on required fees available	
Official guidance on required fees	https://www.trovanorme.salute.gov.it/norme/dettaglioAtto?id=92075
National legal framework in place	N/A
Applicable national legal framework/reference	
Additional information	N/A
Timelines Ethical Review	

Medical Device	Italy
General timespan for single-centre studies (max nr days)	30 - non invasive class I and class IIa-IIb MD; 45 - invasive class IIa-IIb and classe III
General timespan for multi-centre studies (max nr days)	30 - non invasive class I and class IIa-IIb MD; 45 - invasive class IIa-IIb and classe III
Clock-stop possible if complementary information requested	Yes
Timespan counted from	Date of submission of valid application
National legal framework in place	No
Applicable national legal framework/reference	N/A
Additional information	European Regulation 2017/745 (MDR)
Amendments/Substantial Amendments	
Ethical review mandatory for	Any substantial amendments
Responsible for submission of SA	Not specified
Standard notification form available	No
Standard notification form	
Timeline for approval of SA (max nr days)	38
Guidance of submission of SA available	
Guidance on submission of SA	N/A
National legal framework in place	No
Applicable national legal framework/reference	N/A
Additional information	
Safety Reporting	
Reportable AEs	SAE (Serious Adverse Event) SADE (Serious Adverse Device Effect)
Investigator shall report SAE to	Not specified
Reporting timeline	Not specified
Responsible for AE reporting to relevant EC(s)	Sponsor Principal Investigator
SUSAR being life-threatening or leading to death must be reported	Not specified
All other SUSAR must be reported	Not specified
SAE/SADE must be reported	Not specified
Sponsor is obliged to notify all investigators of SAE/SADE occurence	Yes
National standard reporting form available	Not specified

Medical Device	Italy
Standard reporting form	N/A
Reporting format - options	N/A
Preferred format	N/A
Online safety reporting portal	N/A
Provision of annual safety report mandatory	N/A
Annual safety report shall be provided by sponsor to	N/A
Guidance on AE reporting procedure available	No
Guidance on AE reporting procedure	
National legal framework in place	No
Applicable national legal framework/reference	N/A
Additional information	SAE/SADE must be reported to EC(s) for interventional clinical investigations on MD.
End of trial	
End of trial declaration mandatory	Yes
Responsible for end of trial declaration	Sponsor
Regular termination - declaration of timespan (max nr days)	Not specified
Timespan counted from	Not specified
Early/premature termination - declaration timespan (max nr days)	Not specified
Reasons for early termination shall be clearly declared	N/A
Standard declaration form available	N/A
Standard declaration form	N/A
Guidance on end of trial declaration available	N/A
Guidance on end of trial declaration	N/A
National legal framework in place	N/A
Applicable national legal framework/reference	N/A
Additional information	The sponsor shall declare the end of the trial (preliminary or scheduled) to the CA and the ECs.
Additional Information & Specifics	
Additional Information & Specifics	N/A
Study Specific Requirement	
Sponsor	

Medical Device	Italy
Sponsor - Definition available in national law	No
Sponsor - Definition (pursuant to national law)	N/A
Sponsorship mandatory	Yes
Sponsorship mandatory - Additional information	
Co-Sponsor - Definition available in national law	No
Co-Sponsor - Definition (pursuant to national law)	N/A
Co-sponsorship allowed	No
Legal representative based in the EU/EEA is mandatory where Sponsor is located outside EU/EEA:	Yes
Additional Information	N/A
Investigator	
Entitled to be principal investigator	MD
Additional Information	N/A
Study participants - informed consent	
Standard IC form (ICF) available	Not specified
Standard IC form (ICF)	
Standard ICF - Additional Information	N/A
IC is regulated by law	Yes
Informed Consent - Definition/ Requirements	Same rules as for medicinal products apply. European Regulation 536/2014.
Applicable national legal framework/ Reference	N/A
Additional Information	https://www.aifa.gov.it/documents/20142/1619588/linee_indirizzo_centro_coordinamento_20_05_2022.pdf
Study participants - vulnerable population	
Minors / Children - Studies allowed	Yes Pediatric National EC
Specific provision	
Legal framework/Reference (Minors/Children)	Section 4 of Legislative Decree n. 211
Incapacitated persons - Studies allowed	Yes Legal Representative for patients unable to express the informed consent
Specific provisions	Same rules as for IMP trials
Legal framework / Reference (Incapacitated persons)	
Emergency situations - Studies allowed	No national legal framework available
Specific provisions	Same rules as for IMP trials.

Medical Device	Italy
Emergency situation without prior consent of patient or proxy - Studies allowed	Not specified
Conditions allowing trial participation in emergency setting without prior consent	N/A
Legal framework / Reference (Emergency Situation)	N/A
Pregnant or breastfeeding women - Studies allowed	No national legal framework available
Specific provisions	N/A
Legal framework / Reference (Pregnant or breastfeeding women)	N/A
National legal framework for protection of vulnerable populations in place	N/A
Applicable legal framework / Reference (Vulnerable Population)	N/A
Guidelines & conventions for protection of vulnerable populations	N/A
Additional Information	N/A
Study participants - compensation & reimbursement	
Reimbursement for study participants	Optional
Compensation is limited to/provided for	No specific provisions
Additional Information	N/A
Study participants - recriutment & trial outcome >> end of study	
Mandatory to inform participant of clinical trial outcome	Case by case
Additional information	N/A
Data protection	
Notification to DP Authority/ Ombudsmann is mandatory	No
Approval/authorisation required	No
Specific notification timelines before operations start	Not specified
Laguage of notification	N/A
Notification format	Not specified
Notification fee required	N/A
Fee	N/A
Guidance on notification requirements available	N/A
Guidance on notification requirements	N/A

Medical Device	Italy
Data protection authority/agency - contact details	Italian Data Protection Authority DPA - Garante per la Protezione dei Dati Personali
Contact name 2	N/A
Contact name 3	N/A
Phone	+39 06.696771 and +39 06.69677.2917
Fax	N/A
E-mail	rp@gpdp.it
Web address	protocollo@gpdp.it and urp@gpdp.it
Address	Piazza Venezia 11
ZIP/City	00187 Rome
Country	Italy
Additional information	
Archiving & data management	
Study documents must be kept at least (in years)	25
National legal framework in place	No
Applicable national legal framework/reference	N/A
Additional information	European Regulation 536/14
National Legislations	
General Information	
Official website providing relevant national legislation available	Yes
Official website providing relevant national legislation	https://www.salute.gov.it/portale/news/p3_2_1_1_1.jsp?lingua=italiano&menu=notizie&p=dalministero&id=6174
Official governmental legal database available	N/A
Official governmental legal database	N/A
Additional information	The national legislation related to medical device studies is less specific than the legislation concerning IMP trials.
Investigations on Medical Devices	
Applicable national regulations	Transposition of EU Directives on MD
Act on Medical Devices (or comparable national legal framework)	N/A
Transposition of Directive 90/385/EEC	https://www.trovanorme.salute.gov.it/norme/dettaglioAtto?id=88953 - Legislative Decree n.137 (5 august 2022).
Transposition of Directive 93/42/EEC	https://www.trovanorme.salute.gov.it/norme/dettaglioAtto?id=88953 - Legislative Decree n.137 (5 august 2022).
Transposition of Directive 98/79/EC	https://www.normattiva.it/uri-res/N2Ls?urn:nir:stato:decreto.legislativo:2022-08-05;138~art18 - Legislative Decree n.138 (5 august 2022) on in vitro diagnostic medical devices
Transposition of Directive 2007/47/EC	N/A

Medical Device	Italy
Other applicable regulations / implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)	
Additional Information	https://www.salute.gov.it/portale/dispositiviMedici/dettaglioContenutiDispositiviMedici.jsp?lingua=italiano&id=5919&area=dispositivi-medici&menu=settoredm&tab=1#
Combination studies (IMP/MD)	
Applicable national regulations	Legal framework for both study types must be considered
Legal act applicable to both study types	
Other applicable regulations/implementing provisions (acts, laws, decrees, ordinances, circulars, etc)	N/A
Additional information	N/A
Radiation & Radiotherapy	
Specific framework available	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
Additional information	N/A
Biobanking	
Specific framework available	
Applicable legal framework	UNI/ISO 20387 Biotechnology and Biobanking General requirements for biobanking elaborated by the Working Group 2 (WG2) of the ISO/TC 276 Biotechnology e on August 2018
Additional information	N/A
Data protection	
Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)	No national legal framework available
National DP act	
Implementing decrees / ordinances	N/A
Other applicable regulations (covering DP related issues)	European Regulation 2016/679
Additional Information	N/A
Insurance	
Specific requirements	
Applicable legal framework	N/A
Additional information	N/A
EC operations/ Fees	
Separate legal framework available	

Medical Device	Italy
Applicable legal framework	N/A
Additional information	N/A
CA operations/ Fees	
Separate legal framework available	
Applicable legal framework	N/A
Additional information	N/A
Additional Information & Specifics	
Additional Information & Specifics	N/A
Definitions	
MD/MD Investigation	
MD - Definition available in national law	Yes
MD - Definition	According to the Regulation 2017/745, art.2: 'Medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: — diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease, — diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability, — investigation, replacement or modification of the anatomy or of a physiological or pathological process or state, — providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.
Investigation of MD - Definition available in national law	N/A
MD Investigation - Definition	N/A
Additional Information	N/A
Further Definitions	
Additional information	N/A
Additional Information & Specifics	
Additional Information & Specifics Additional Information & Specifics	N/A