Medical Device	Poland
Competent Authority	
Contact Details	
Contact name 1	The President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
Contact name 2	
Contact name 3	
Phone	+48 22 492 11 00
Fax	+48 22 492 11 09
Email General	urpl@urpl.gov.pl
Email Department	dim@urpl.gov.pl
Address	Al. Jerozolimskie 181C
ZIP/City	02-222 Warszawa
Country	Poland
Web address	https://urpl.gov.pl/en
Additional information	
Clinical Investigation Authorisation / Registration / Notification	
Regulatory & ethics bodies involved in approval proccess	Competent Authority/-ies (CA) Ethics committee(s)
CA - Submission for authorisation mandatory for...	All clinical trials on Medicinal Products (MP)
CE-marked MD used within label are exempted from any notification obligation to CA	Yes
Guidance on submission of application available	Yes
Guidance on submission of application	Act of 7 April 2022 on medical devices (Dz.U. 2022 poz. 974 - https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20220000974/U/D20220974Lj.pdf)
National legal framework in place	Yes
Applicable national legal framework/reference	Act of 7 April 2022 on medical devices (Dz.U. 2022 poz. 974 - https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20220000974/U/D20220974Lj.pdf)
Additional information	
Submission Format	
Online portal	
Standard application form available	Yes

Medical Device	Poland
Standard application form	A Standard Application From for submission to the CA and the EC: "Wzór wniosku o wydanie pozwolenia na prowadzenie badania klinicznego"; available on the CA website (in Polish).
Standard application form - additional information	
Use of standard application form binding	Not applicable
Guidance on submission format available	No
Guidance on submission format	
National legal framework in place	No
Applicable national legal framework/reference	
Additional information	
Language of Submission	
Language(s) of application	Polish English
English accepted	Partly, not for all documents
Documents mandatory to be in official national language	Information material, Documents and Forms intended for study participants and patient information
National legal framework in place	Yes
Applicable national legal framework/reference	Act of 7 April 2022 on medical devices (Dz.U. 2022 poz. 974 - https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20220000974/U/D20220974Lj.pdf)
Additional information	
Submission Fees	
Fees for trial submission mandatory	Yes
Fees	Fees for authorization: 1) Clinical investigation: 7000 PLN (approx. € 1700.-) 2) Amendments: 3000 PLN (approx. € 720.-)
Waiver for academic (non-commercial) studies possible	No
Payment requirements (timelines)	Prior to submission of application
Official guidance on required fees available	Yes
Official guidance on required fees	Act of 7 April 2022 on medical devices (Dz.U. 2022 poz. 974 - https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20220000974/U/D20220974Lj.pdf)

Medical Device	Poland
National legal framework in place	Yes
Applicable national legal framework/reference	Act of 7 April 2022 on medical devices (Dz.U. 2022 poz. 974 - https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20220000974/U/D20220974Lj.pdf)
Additional information	
Timelines Autorisation	
General timespan (maw nr days)	45
Mode of approval	Explicit
Clock-stop possible if complementary information requested	Yes
National legal framework in place	Yes
Applicable national legal framework/reference	Act of 7 April 2022 on medical devices (Dz.U. 2022 poz. 974 - https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20220000974/U/D20220974Lj.pdf)
Additional information	
Amendments/Substantial Amendments	
Standard notification form	
Timeline for approval of SA (max nr days)	38
Guidance of submission of SA available	Yes
Guidance of submission of SA	Act of 7 April 2022 on medical devices (Dz.U. 2022 poz. 974 - https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20220000974/U/D20220974Lj.pdf)
National legal framework in place	Yes
Applicable national legal framework/reference	Act of 7 April 2022 on medical devices (Dz.U. 2022 poz. 974 - https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20220000974/U/D20220974Lj.pdf)
Additional information	
Safety Reporting	
Sponsor must declare reportable events to	National CA Relevant EC(s)
Investogator/PI shall separately report any SAE/SADE to CA	No
Reportable AEs	SAE (Serious Adverse Event) SADE (Serious Adverse Device Effect) Any events with the potential to influence safety of a subject
SUSAR being life-threateningor leading to death must be reported	Within a max of 7d from the day when the event occurred
All other SUSARs	As soon as possible

Medical Device	Poland
SAE/SADE must be reported	As soon as possible
National standard reporting form available	Yes
Standard reporting form	"Form for medical incident notification"/ "Formularz zgłoszenia incydentu medycznego" (in en/pl). Form available on the URPL website.
Reporting format - options	N/A
Online safety reporting portal	N/A
Provision of annual safety report mandatory	Yes
Annual safety report shall be provided by sponsor to	National CA
Guidance on AE reporting procedure available	N/A
Guidance on AE reporting procedure	N/A
National legal framework in place	Yes
Applicable national legal framework/reference	Art 51 Medical Device Act 2010 (en) / Dz.U. 2010 nr 107 poz. 679 (pl)
Additional information	An annual safety report shall be submitted to the CA clinical investigations on MD (interventional and observational) and registries (MD CE-marked used within label are exempted from this obligation).
End of trial	
End of trial declaration: who, when, what?	All clinical trials requiring authorisation by CA
Responsible for end of trial declaration	Sponsor
Regular termination - declaration of timespan (max nr days)	90
Timespan counted from	N/A
Early/premature termination - declaration timespan (max nr days)	15
Reasons for early termination shall be clearly declared	Yes
Standard declaration form available	N/A
Standard declaration form	N/A

Medical Device	Poland
Guidance on end of trial declaration available	N/A
Guidance on end of trial declaration	N/A
National legal framework in place	Yes
Applicable national legal framework/reference	Art 54 Medical Device Act 2010 (en) Health Minister Order 15 Nov 2010 (related details on the final report)
Additional information	In case of a multinational investigation, the relevant bodies of the Member States shall be notified of completing the clinical investigation. Premature termination: The sponsor shall also notify the relevant bodies of the Member State and the European Commission if the investigation has been early terminated due to safety considerations.
Additional Information & Specifics	
Additional Information & Specifics	Summary of the description of the URPL Office related to medical devices: President of the Office is a government administrative authority, competent for matters concerning marketing and use of medical devices – within the meaning and on the basis of the Act on Medical Devices of 20 May 2010 (O.J. No 107, item 679) and clinical trials within the scope determined by the Medical Devices Act of 20 May 2010. The Office is a public administration body supporting the President of the Office in realization of the above matters. The rules and the scope of responsibilities is determined by the Act of 18 March 2011 on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.
Ethics Committee	
Contact Details	
Contact name 1	Local independent Research Ethics Committees (in Poland named „Bioethics Committees“)
Contact name 2	50 local RECs
Contact name 3	N/A
Phone	N/A
Fax	N/A
Email General	N/A
Email Department	N/A
Address	N/A
ZIP/City	N/A
Country	N/A
Web address	http://www.oil.org.pl/xml/oil/oil68/tematy/komisje/stale/bioetyki/komisje
Additional information	Local RECs are established at academic institutions (e.g. medical universities), non-university medical research centres and health institutes or at the Regional Chambers of Physicians and Dentists. List of ECs is provided on the website of the Regional Chamber of Physicians and Dentists in Warsaw (Okręgowa Izba Lekarska). No central Ethics Committee.
Ethical Review - General	
Submission for Ethical review mandatory for	All clinical investigations of MD

Medical Device	Poland
Submission to CA and EC to be performed in the following order	Not specified
Procedural interaction between CA and EC during approval proccess	N/A
Procedural interaction - additional information	N/A
Additional information	N/A
Single-Centre Studies - Ethical Review	
Ethical approval (favourable opinion) to be obtained from	Local EC
Additional information	The competent local Research Ethics Committee (“Bioethics Committee”) issues its reasonable opinion on the application of the clinical investigation.
Multi-Centre Studies - Ethical Review	
Ethical approval (favourable option) required form	Lead EC + All concerned local ECs for site-specific assessment
Submission of application required to	Lead EC (authorised to issue a single opinion)
Additional information	The sponsor shall appoint a coordinator of clinical investigation from among all the clinical investigators involved in a multi-centre clinical investigation (Art 42 Medical Device Act 2010). The sponsor or the designated coordinator shall submit the application to the EC (“Bioethics Committee”) where the coordinating investigator has his/her registered office. This EC, acting as “lead” EC, shall inform all other ECs of the involved trial sites on the envisaged participation. They have 14 days to perform a site-specific assessment and submit reservations concerning the participation of the investigator or site in the clinical investigation. The designated “lead” EC is authorized to issue a binding “single opinion” on the clinical investigation on behalf of the other involved ECs. (Art 49 Medical Device Act 2010)
Submission of Application	
Responsible for study submission	Sponsor
Entitled to study submission	N/A
Prerequisites for submission	Positive opinion by relevant EC(s)
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	Art 51 Medical Device Act 2010 (en) / Dz.U. 2010 nr 107 poz. 679 (pl)

Medical Device	Poland
Additional information	The sponsor shall submit the request for approval of the clinical investigation to the local REC of the trial site. In case of a multi-centre investigation it shall be submitted to the EC where the coordinating clinical investigator has its registered office.
Submission Format	
Format option(s)	Paper hardcopy
Preferred format	N/A
Online portal	N/A
Standard application form available	Yes
Standard application form	Form for submission of the clinical investigation to the CA and the EC (Wzór wniosku o wydanie pozwolenia na prowadzenie badania klinicznego) is available on the CA website (in Polish). The application form is also provided in Annex 1 (Załącznik Nr.1) of Health Minister Order 15 Nov 2010.
Standard application form - additional information	N/A
Use of standard application form binding	N/A
Guidance on submission format available	Yes
Guidance on submission format	The application documentation is specified in Art 44(3) (1-10) Medical Device Act 2010 (en)/ Dz.U. 2010 nr 107 poz. 679 (pl).
National legal framework in place	Yes
Applicable national legal framework/reference	Art 44(3) (1-10) Medical Device Act 2010 (en)/ Dz.U. 2010 nr 107 poz. 679 (pl) Annex 1 (Załącznik Nr.1) of Health Minister Order 15 Nov 2010
Additional information	N/A
Language of Submission	
Language(s) of application	Polish English
Preferred language of application	N/A
English accepted	Partly, not for all documents
Documents mandatory to be in official national language	Information material, Documents and Forms intended for study participants and patient information
Documents mandatory to be in local language of study site	N/A
Documents mandatory to be in language of study participant	N/A
National legal framework in place	N/A

Medical Device	Poland
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	Not specified
Fees for ethical review	Depending on EC concerned: each regional Ethics Committee has its own payment criteria; eg Bioethics Commission Jagiellonian University: Single center trial 1500 Euro Multi-centre trial: 1500 Euro + 250 Euros for each subsequent examination center
Official guidance on required fees available	N/A
Official guidance on required fees	N/A
National legal framework in place	N/A
Applicable national legal framework/reference	N/A
Additional information	N/A
Timelines Ethical Review	
General timespan for single-centre studies (max nr days)	60
General timespan for multi-centre studies (max nr days)	60
Clock-stop possible if complementary information requested	Yes
Timespan counted from	Date of receipt of valid application
National legal framework in place	N/A
Applicable national legal framework/reference	N/A
Additional information	N/A
Amendments/Substantial Amendments	
Ethical review mandatory for	Any substantial amendments
Responsible for submission of SA	Sponsor
Standard notification form available	Yes

Medical Device	Poland
Standard notification form	Depending on EC concerned: each regional Ethics Committee has its own payment criteria. eg Bioethics Commission Jagiellonian University: Single center trial 1500 Euro Multi-centre trial: 1500 Euro + 250 Euros for each subsequent examination center
Timeline for approval of SA (max nr days)	60
Guidance of submission of SA available	N/A
Guidance on submission of SA	N/A
National legal framework in place	N/A
Applicable national legal framework/reference	N/A
Additional information	NB! A positive opinion of the competent EC is a prerequisite for application to the CA.
Safety Reporting	
Reportable AEs	SAE (Serious Adverse Event) SADE (Serious Adverse Device Effect) Any events with the potential to influence safety of a subject
Investigator shall report SAE to	Sponsor
Reporting timeline	Immediately (without delay)
Responsible for AE reporting to relevant EC(s)	Sponsor
SUSAR being life-threatening or leading to death must be reported	Immediately (without delay) Within a max of 7d from the day when the event occurred
All other SUSAR must be reported	N/A
SAE/SADE must be reported	Immediately (without delay) Within a max of 7d from the day when the event occurred
Sponsor is obliged to notify all investigators of SAE/SADE occurence	N/A
National standard reporting form available	Yes
Standard reporting form	"Form for medical incident notification"/ "Formularz zgłoszenia incydentu medycznego" (in en/pl). Available on URPL website in section: Wyroby Medyczne » Nadzor Rynku » Formularze.
Reporting format - options	N/A
Preferred format	N/A
Online safety reporting portal	N/A
Provision of annual safety report mandatory	N/A

Medical Device	Poland
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	Yes
Applicable national legal framework/reference	Art 51 Medical Device Act 2010 (en) / Dz.U. 2010 nr 107 poz. 679 (pl)
Additional information	
End of trial	
End of trial declaration mandatory	Yes
Responsible for end of trial declaration	Not specified
Regular termination - declaration of timespan (max nr days)	15
Timespan counted from	N/A
Early/premature termination - declaration timespan (max nr days)	N/A
Reasons for early termination shall be clearly declared	Yes
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	Art 51 Medical Device Act 2010 (en) / Dz.U. 2010 nr 107 poz. 679 (pl)
Additional information	Premature termination of the clinical investigation: The sponsor shall also notify the relevant bodies of the Member State and the European Commission if the investigation has been early terminated due to safety considerations.
Additional Information & Specifics	
Additional Information & Specifics	N/A

Medical Device	Poland
Study Specific Requirement	
Sponsor	
Sponsor - Definition available in national law	Yes
Sponsor - Definition (pursuant to national law)	Definition of sponsor pursuant to Art 2 (28) Medical Device Act 2010: “Any entity responsible for initiating and conducting a clinical investigation having the place of residence or the registered office in a Member State or acting solely through the agency of its legal representative having the place of residence or the registered office in a Member State”. Definition of Authorised representative: see Art 2 (2) Medical Device Act 2010.
Sponsorship mandatory	Yes
Sponsorship mandatory - Additional information	
Co-Sponsor - Definition available in national law	No
Co-Sponsor - Definition (pursuant to national law)	
Co-sponsorship allowed	No
Legal representative based in the EU/EEA is mandatory where Sponsor is located outside EU/EEA:	Yes
Additional Information	
Investigator	
Entitled to be principal investigator	N/A
Additional Information	The investigator may be a doctor or another person with professional qualifications necessary to perform a clinical investigation of a MD (pursuant to Art 40 Medical Device Act 2010) In the case of clinical investigation of Active implantable MD, the clinical investigator may only be a doctor. In terms of qualification, the clinical trials directive and guidlines (Volume 10), ICH E6 apply (qualified by training and experience).
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	Prior to the commencement of a clinical investigation with MD, informed consent must be obtained from study subjects according to the provisions specified in the national law.
Applicable national legal framework/ Reference	Art 40 (4) and 56 Medical Device Act 2010 (en) Art 37b (2) and Art. 37f Pharmaceutical Law 2001 (en) Art 25 (1) Physician’s Profession Act 1996 (Dz.U. 1997 nr 28 poz.152)
Additional Information	Special provisions apply to vulnerable populations such as minors, incapacitated adults and subjects in emergency situations (Art 40 (4,10,11,13) Medical Device Act 2010).

Medical Device	Poland
Study participants - vulnerable population	
Minors / Children - Studies allowed	Yes Special provisions apply
Specific provision	Clinical investigations with MD on minors are possible under special provisions. Clinical trials on minors include trials on: preterm newborns, full-term newborns (0-27 days), infants and small children (28 days-23 months), children (24 months-11 years) and teenagers (12-18 years). A specific regulation issued by the Minister of Health covers in detail the provisions for the conduct of clinical trials on minors: Order of the Minister of Health 30 April 2004 (Dz.U. 2004 nr 104 poz. 1108)
Legal framework/Reference (Minors/Children)	Art 40 (10) Medical Device Act 2010 (en) Order of the Minister of Health 30 April 2004 (Dz.U. 2004 nr 104 poz. 1108)
Incapacitated persons - Studies allowed	Yes Special provisions apply
Specific provisions	
Legal framework / Reference (Incapacitated persons)	Art 40 (11-13) Medical Device Act 2010 (en) Art 26 (2&3) of Act of 5 December 1996 on the professions of a physician and a dentist
Emergency situations - Studies allowed	Yes Special provisions apply
Specific provisions	
Emergency situation without prior consent of patient or proxy - Studies allowed	Not specified
Conditions allowing trial participation in emergency setting without prior consent	
Legal framework / Reference (Emergency Situation)	Art 40 (11-13) Medical Device Act 2010 (en)
Pregnant or breastfeeding women - Studies allowed	Yes Special provisions apply
Specific provisions	
Legal framework / Reference (Pregnant or breastfeeding women)	Art 26(1&2) Physician’s Profession Act 1996 (Dz.U. 1997 nr 28 poz. 152) Not explicitly mentioned in Medical Device Act 2010.
National legal framework for protection of vulnerable populations in place	No
Applicable legal framework / Reference (Vulnerable Population)	

Medical Device	Poland
Guidelines & conventions for protection of vulnerable populations	
Additional Information	
Study participants - compensation & reimbursement	
Reimbursement for study participants	Permissible
Compensation is limited to/provided for	N/A
Additional Information	No incentives or financial inducements shall be given to study subjects, except compensation for any expenses incurred (pursuant to Art 40 (9) Medical Device Act 2010). Payment may be made to healthy volunteers of age taking part in bioavailability studies, or Phase I studies conducted in Poland.
Study participants - recriutment & trial outcome >> end of study	
Mandatory to inform participant of clinical trial outcome	N/A
Additional information	N/A
Data protection	
Notification to DP Authority/ Ombudsmann is mandatory	Yes
Approval/authorisation required	No
Specific notification timelines before operations start	Not specified
Laguage of notification	N/A
Notification format	N/A
Notification fee required	N/A
Fee	N/A
Guidance on notification requirements available	N/A
Guidance on notification requirements	N/A
Data protection authority/agency - contact details	The Inspector General for Personal Data Protection - GIODO
Contact name 2	N/A
Contact name 3	N/A
Phone	+48 22 860 70 86
Fax	+48 22 860 70 86
E-mail	kancelaria@giodo.gov.pl

Medical Device	Poland
Web address	http://www.giodo.gov.pl/
Address	ul. Stawki 2
ZIP/City	00-193 Warszawa
Country	Poland
Additional information	Notification of clinical investigations to GIODO is required for all clinical investigations of MD. The right for the subject to personal data protection shall be safeguarded according to Art 40 (4.3) and 55 Medical Device Act 2010 and the Act on Patients' Rights and the Spokesman for the Patients' Rights 6 November 2008 (Dz.U. 2009 nr 52 poz. 417: Before obtaining consent, the investigator shall inform the participant, that source documents will be available for monitoring purposes, internal and external audits. The sponsor must archive the documentation of a study for 5 years starting from the beginning of the year after the study was completed unless a contract between the sponsor and the investigator defines a different time period (Art. 37ra. par. 1).
Archiving & data management	
Study documents must be kept at least (in years)	5
National legal framework in place	Yes
Applicable national legal framework/reference	Art 55 (4) Medical Device Act 2010
Additional information	N/A
National Legislations	
General Information	
Official website providing relevant national legislation available	Yes
Official website providing relevant national legislation	https://www.urpl.gov.pl/pl/wyroby-medyczne/akty-prawne/przepisy-rp
Official governmental legal database available	Yes
Official governmental legal database	ISAP (Internetowy System Aktów Prawnych, ang. The Internet System of Legal Acts), Online Database system of legal acts containing bibliographic and legal texts published in official publications (the Journal of Laws and the Polish Monitor) issued by the Prime Minister - https://isap.sejm.gov.pl/
Additional information	
Investigations on Medical Devices	
Applicable national regulations	National Act on Medical Devices Transposition of EU Directives on MD
Act on Medical Devices (or comparable national legal framework)	Act of 7 April 2022 on medical devices (Dz.U. 2022 poz. 974 - https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20220000974/U/D20220974Lj.pdf)
Transposition of Directive 90/385/EEC	

Medical Device	Poland
Transposition of Directive 93/42/EEC	
Transposition of Directive 98/79/EC	
Transposition of Directive 2007/47/EC	
Other applicable regulations / implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)	• Act of 6 September 2001 on Pharmaceutical Law (Dz.U. 2001 nr 126 poz. 1381 - https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20011261381/U/D20011381Lj.pdf) • Act of 5 December 1996 on proffesion's of physician and dentis, Article 25 (Dz.U. 1997 nr 28 poz. 152 - https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU19970280152/U/D19970152Lj.pdf) • Order of the Minister of Health of 5 November 2010 for classification of Medical Devices (Dz. U. 2010 nr 215 poz. 1416 - https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20102151416/O/D20101416.pdf) • Regulation of the Minister of Health of 17 February 2016 on essential requirements and conformity assessment procedures for medical devices (Dz.U 2016 poz. 211 - https://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20160000211/O/D20160211.pdf)
Additional Information	
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)	
Additional information	
Radiation & Radiotherapy	
Specific framework available	Yes
Applicable legal framework	Special requirement apply for the use of MD emitting radiation, as specified in: • Council Directive 93/42/EEC of 14 June 1993 concerning medical devices • Regulation of the Minister of Health of 25 August 2005on the conditions for the safe use of ionizing radiation exposure for all types of medical research • Act of 29 November 2000 on Nuclear Law
Additional information	
Biobanking	
Specific framework available	
Applicable legal framework	
Additional information	
Data protection	

Medical Device	Poland
Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)	N/A
National DP act	N/A
Implementing decrees / ordinances	N/A
Other applicable regulations (covering DP related issues)	N/A
Additional Information	N/A
Insurance	
Specific requirements	N/A
Applicable legal framework	N/A
Additional information	N/A
EC operations/ Fees	
Separate legal framework available	N/A
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	
Definitions	
MD/MD Investigation	
MD - Definition available in national law	Yes

Medical Device	Poland
MD - Definition	Definition is in line with the provisions of the Regulation 2017/745: "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. The following products shall also be deemed to be medical devices: • devices for the control or support of conception; • products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.
Investigation of MD - Definition available in national law	Yes
MD Investigation - Definition	Definition is in line with the provisions of the Regulation 2017/745: "clinical investigation' means any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device;"
Additional Information	
Further Definitions	
Additional information	
Additional Information & Specifics	
Additional Information & Specifics Additional Information & Specifics	