Medical Device	Germany
Competent Authority	
Contact Details	
Contact name 1	National Competent Autority (NCA) /federal higher authority ("Bundesoberbehörde- BOB")
Contact name 2	Federal Institute for Drugs and Medical Devices*:Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) for medical devices
Contact name 3	Abteilung Medizinprodukte/ Department Medical Devices
Phone	+49 (0)228 99 307-5999
Fax	+49-228-2075207
Email General	
Email Department	
Address	Kurt-Georg-Kiesinger-Allee 3
ZIP/City	53175 Bonn
Country	Germany
Web address	Federal Institute for Drugs and Medical Devices: http://www.bfarm.de/EN
Additional information	BfArM is responsible for clinical investigations of medical devices and for performance test of in vitro diagnostic agents, with the exception of those for which the Paul-Ehrlich-Institute is responsible.
Clinical Investigation Authorisation / Registration / Notification	
Regulatory & ethics bodies involved in approval proccess	National Competent Authorities Ethics committee(s) For clinical trials (and performance tests) according to EU 745/2017 (and 746/2017)
CA - Submission for authorisation mandatory for...	clinical trials (and performance tests) according to EU 745/2017 (Art. 62 and Art 74) (and 746/2017).
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.bfarm.de/EN/Medical-devices/_FAQ/Clinical-investigations-performance-studies/Application-for-authorisation/faq-liste
National legal framework in place	Yes
Applicable national legal framework/reference	Medizinprodukterecht-Durchführungsgesetz (MPDG)

Medical Device	Germany
Additional information	An approval or notification process is not required, if within the clinical trial the MD is used within the intended use label and without additional invasive or stressful procedures beyond the normal conditions of use of the product (§ 47 (3) Medizinprodukterecht-Durchführungsgesetz (MPDG)). Furthermore, notification to NCA instead of approval is possible for “sonstige klinische Prüfungen” (other clinical trials) according to §3 (4) MPDG. Exemptions for “sonstige klinische Prüfungen” (other clinical trials) apply, if a clinical trial is a) not part of a systematic and planned product development process or the Product observation of a current or future manufacturer, b) is not carried out with the aim of ensuring the conformity of a product with the requirements of Regulation (EU) 2017/745, c) serves to answer scientific or other questions, d) outside of a clinical development plan according to Annex XIV Part A Number 1 Letter a of Regulation (EU) 2017/745. Regarding "CE-marked MD used within label are exempted from any notification obligation to CA" ticked "NO": *These are not clinical trials or performance studies requiring approval according to the MDR or the IVDR if the medical device is used exclusively within the scope of its intended purpose (strictly according to the instructions for use, incl. indications, contraindications, etc.) and no additional invasive or stressful examinations are carried out. In general, however, professional guidelines for the physicians involved must be observed and an appropriate ethics committee must be involved. Furthermore, Art 74 of the EU-Regulation 745/2017 (PMCF) is valid.*
Submission Format	
Online portal	DMIDS - German Medical Devices Information and Database System
Standard application form available	Yes
Standard application form	Application form of the portal of the German Medical Devices Information and Database System - DMIDS Guidance document https://www.bfarm.de/SharedDocs/Downloads/EN/MedicalDevices/DMIDS_guidance_sponsors.html?nn=965000
Standard application form - additional information	
Use of standard application form binding	Yes
Guidance on submission format available	Yes
Guidance on submission format	https://www.bfarm.de/EN/Medical-devices/Portals/DMIDS/_node.html
National legal framework in place	Yes
Applicable national legal framework/reference	**Medizinprodukterecht-Durchführungsgesetz (MPDG)**
Additional information	It is mandatory to use the DMIDS portal for trial submission. The NCAs and the ECs will be informed automatically via DMIDS. Language of the DMIDS is German.
Language of Submission	
Language(s) of application	German English
English accepted	Yes
Documents mandatory to be in official national language	Protocol Summary Information material, Documents and Forms intended for study participants and patient information Information on safe use of MD

Medical Device	Germany
National legal framework in place	Yes
Applicable national legal framework/reference	MPDG Art. 38 https://www.gesetze-im-internet.de/mpdg/__38.html
Additional information	
Submission Fees	
Fees for trial submission mandatory	Yes
Fees	For clinical trials according to Art. 71, 75 and 80 MDR - Clinical trials: 2.000 – 9.900 EURO - Substantial Amendments: 600- 2.000 EURO - Notification of SAE: 100 - 400 EURO See “Besondere Gebührenverordnung BMG” (Special Fee Ordinance BMG) – BMGBGebV Annex section 8 and 9. For “sonstige klinische Prüfungen” according to § 47 (3) MPDG (CE-marked device within intended use and no additional invasive/harmful procedures), no approval/notification of NCA is needed, therefore no fees apply.
Waiver for academic (non-commercial) studies possible	No
Payment requirements (timelines)	No info indicated
Official guidance on required fees available	Yes
Official guidance on required fees	See “Besondere Gebührenverordnung BMG” (Special Fee Ordinance BMG) – BMGBGebV Annex section 8 and 9. Fees for Ethic Committees are subject to the fee regulations of the federal states and ECs, respectively.
National legal framework in place	Yes
Applicable national legal framework/reference	See “Besondere Gebührenverordnung BMG” (Special Fee Ordinance BMG) – BMGBGebV Annex section 8 and 9.
Additional information	
Timelines Autorisation	
General timespan (maw nr days)	According to MDR (EU regulation 745/2017)
Mode of approval	According to MDR (EU regulation 745/2017)
Clock-stop possible if complementary information requested	Not specified
National legal framework in place	Yes
Applicable national legal framework/reference	**Medizinprodukterecht-Durchführungsgesetz (MPDG)**

Medical Device	Germany
Additional information	Application for a decision on the authorisation requirement of a clinical trial of a medical device or a performance study of an in vitro diagnostic medical device: If the regulatory classification of a planned clinical investigation or performance study cannot be clarified, the parties involved in the conduct, authorisation or monitoring of the clinical investigation / performance study (see below) may submit an application for a decision on the authorisation requirement to the higher federal authority in accordance with Section 6(3) MPDG. For a decision on the authorisation requirement by the BfArM, an informal application for a decision on the authorisation requirement can be submitted to the BfArM in accordance with Section 6 (3) MPDG. (Application for a decision on the authorisation requirement of a clinical trial of a medical device or a performance study of an in vitro diagnostic medical device) Decision tree on the application and notification procedures according to MDR / MPDGBfArM's decision tree
Amendments/Substantial Amendments	
Standard notification form	Submission of substantial amendments to NCA and EC viaDIMDS platform.
Timeline for approval of SA (max nr days)	According to MDR (EU regulation 745/2017)
Guidance of submission of SA available	
Guidance of submission of SA	
National legal framework in place	N/A
Applicable national legal framework/reference	
Additional information	
Safety Reporting	
Sponsor must declare reportable events to	According to MDR (EU regulation 745/2017) and § 64 MPDG
Investogator/PI shall separately report any SAE/SADE to CA	
Reportable AEs	According to MDR (EU regulation 745/2017) and § 64 MPDG
SUSAR being life-threateningor leading to death must be reported	Not specified
All other SUSARs	Not specified
SAE/SADE must be reported	According to MDR (EU regulation 745/2017) and § 64 MPDG
National standard reporting form available	According to MDR (EU regulation 745/2017)
Standard reporting form	MDCG-SAE reporting table (see appendix of the MDCG guideline)
Reporting format - options	Electronically
Online safety reporting portal	
Provision of annual safety report mandatory	
Annual safety report shall be provided by sponsor to	Not specified

Medical Device	Germany
Guidance on AE reporting procedure available	No
Guidance on AE reporting procedure	
National legal framework in place	Yes
Applicable national legal framework/reference	§ 64 MPDG
Additional information	Reporting of serious adverse events (SAEs) and device deficiencies (DDs) for clinical investigations
End of trial	
End of trial declaration: who, when, what?	According to MDR (EU regulation 745/2017) and § 64 MPDG
Responsible for end of trial declaration	Sponsor
Regular termination - declaration of timespan (max nr days)	According to MDR (EU regulation 745/2017) and § 64 MPDG
Timespan counted from	Not specified
Early/premature termination - declaration timespan (max nr days)	According to MDR (EU regulation 745/2017) and § 64 MPDG
Reasons for early termination shall be clearly declared	Yes
Standard declaration form available	
Standard declaration form	
Guidance on end of trial declaration available	
Guidance on end of trial declaration	
National legal framework in place	Yes
Applicable national legal framework/reference	§ 65 MPDG
Additional information	
Additional Information & Specifics	
Additional Information & Specifics	The competent regional authority ("Landesbehörde") is automatically informed via the electronic notification process; no specific application required.
Ethics Committee	
Contact Details	
Contact name 1	52 local ECs

Medical Device	Germany
Contact name 2	N/A
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.ak-med-ethik-komm.de/index.php/de/mitglieder
Additional information	EC approval has to be applied by the responsible EC via DMIDS BEFORE CTA (sequential process). Responsible EC is the public law EC appointed to the investigator, Principal Investigator or Lead investigator, if appropriate (according to § 33 MPDG). An approval or notification process involving NCAs is not required, if within the clinical trial the MD is used within the intended use label and without additional invasive or stressful procedures beyond the normal conditions of use of the product (§ 47 (3) Medizinprodukterecht-Durchführungsgesetz (MPDG)). However, for this clinical studies as well as for other clinical studies not covered by MDR. CTR or IVDR an advice is required by the responsible EC according to (Model) Professional Code for Physicians in Germany (MBO) Art. 15.
Ethical Review - General	
Submission for Ethical review mandatory for	
Submission to CA and EC to be performed in the following order	
Procedural interaction between CA and EC during approval proccess	Not applicable
Procedural interaction - additional information	
Additional information	
Single-Centre Studies - Ethical Review	
Ethical approval (favourable opinion) to be obtained from	Local EC
Additional information	There are 52 local ECs responsible for studies with human medicines. The local EC depends on the location of the trial site.
Multi-Centre Studies - Ethical Review	
Ethical approval (favourable option) required form	Lead EC (authorised to issue a single opinion)
Submission of application required to	Lead EC + All concerned local ECs for site-specific assessment
Additional information	There are 52 local ECs responsible for studies with human medicines. The responsible EC for clinical trials according to Art. 62, 74 and 82 MDRdepends on the location of the investigator, Principal Investigator or Lead Investigator, if applicable (§ 33 MPDG).
Submission of Application	

Medical Device	Germany
Responsible for study submission	Sponsor
Entitled to study submission	Not specified
Prerequisites for submission	Not specified
Guidance on submission of application available	
Guidance on submission of application	
National legal framework in place	
Applicable national legal framework/reference	
Additional information	
Submission Format	
Format option(s)	Online portal
Preferred format	
Online portal	The portal of German Medical Devices Information and Database System - DMIDS
Standard application form available	
Standard application form	
Standard application form - additional information	
Use of standard application form binding	
Guidance on submission format available	
Guidance on submission format	
National legal framework in place	
Applicable national legal framework/reference	
Additional information	
Language of Submission	
Language(s) of application	German English
Preferred language of application	
English accepted	Partly, not for all documents
Documents mandatory to be in official national language	Protocol Summary Information material, Documents and Forms intended for study participants and patient information Information on safe use of MD

Medical Device	Germany
Documents mandatory to be in local language of study site	Protocol Summary Information material, Documents and Forms intended for study participants and patient information Information on safe use of MD
Documents mandatory to be in language of study participant	Protocol Summary Information material, Documents and Forms intended for study participants and patient information Information on safe use of MD
National legal framework in place	
Applicable national legal framework/reference	
Additional information	
Submission Fees	
Fees for ethical review mandatory	Yes
Waiver for academic (non-commercial) studies possible	Reduced fees are charged
Fees for ethical review	
Official guidance on required fees available	No
Official guidance on required fees	
National legal framework in place	No
Applicable national legal framework/reference	
Additional information	
Timelines Ethical Review	
General timespan for single-centre studies (max nr days)	40 (+ 20 days, if involvement of experts is necessary)
General timespan for multi-centre studies (max nr days)	40 (+ 20 days, if involvement of experts is necessary)
Clock-stop possible if complementary information requested	Yes
Timespan counted from	Receipt of RFI
National legal framework in place	Yes
Applicable national legal framework/reference	§§ 32 – 37 MPDG for clinical trials (approval process) §§ 48 – 52 MPDG for other clinical trials according to MPDG (notification process)
Additional information	
Amendments/Substantial Amendments	
Ethical review mandatory for	Any substantial amendments
Responsible for submission of SA	Sponsor

Medical Device	Germany
Standard notification form available	No
Standard notification form	
Timeline for approval of SA (max nr days)	47 (+ 20 days, if involvement of experts is necessary)
Guidance of submission of SA available	Yes
Guidance on submission of SA	Notification of substantial amendments to the federal CA and all involved ECs is performed by use of the DMIDS.
National legal framework in place	Yes
Applicable national legal framework/reference	§§ 54 – 59 MPDG
Additional information	
Safety Reporting	
Reportable AEs	SAE (Serious Adverse Event) (MDR Art. 2 No 58) device deficiency (MDR Art. 2 No 59)
Investigator shall report SAE to	Not specified
Reporting timeline	Immediately (without delay)
Responsible for AE reporting to relevant EC(s)	Not specified
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	
National standard reporting form available	Not specified
Standard reporting form	
Reporting format - options	Not specified
Preferred format	
Online safety reporting portal	
Provision of annual safety report mandatory	
Annual safety report shall be provided by sponsor to	Not applicable

Medical Device	Germany
Guidance on AE reporting procedure available	
Guidance on AE reporting procedure	
National legal framework in place	Yes
Applicable national legal framework/reference	Art. 80 MDR § 64 MPDG for “sonstige klinische Prüfungen“
Additional information	
End of trial	
End of trial declaration mandatory	Yes
Responsible for end of trial declaration	Sponsor
Regular termination - declaration of timespan (max nr days)	15 (Art. 77 MDR)
Timespan counted from	Not specified
Early/premature termination - declaration timespan (max nr days)	15 Days (in case of termination due to safety concerns 24 hours)
Reasons for early termination shall be clearly declared	
Standard declaration form available	
Standard declaration form	
Guidance on end of trial declaration available	
Guidance on end of trial declaration	
National legal framework in place	Yes
Applicable national legal framework/reference	§ 64 MPDG
Additional information	
Additional Information & Specifics	
Additional Information & Specifics	N/A
Study Specific Requirement	
Sponsor	
Sponsor - Definition available in national law	No
Sponsor - Definition (pursuant to national law)	

Medical Device	Germany
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	
Legal representative based in the EU/EEA is mandatory where Sponsor is located outside EU/EEA:	No
Additional Information	
Investigator	
Entitled to be principal investigator	N/A
Additional Information	N/A
Study participants - informed consent	
Standard IC form (ICF) available	Not specified
Standard IC form (ICF)	
Standard ICF - Additional Information	
IC is regulated by law	Yes
Informed Consent - Definition/ Requirements	
Applicable national legal framework/ Reference	§ 28 MPDG
Additional Information	
Study participants - vulnerable population	
Minors / Children - Studies allowed	Yes According to MDR
Specific provision	
Legal framework/Reference (Minors/Children)	According to MDR
Incapacitated persons - Studies allowed	Yes Special provisions apply
Specific provisions	
Legal framework / Reference (Incapacitated persons)	According to MDR
Emergency situations - Studies allowed	Yes Special provisions apply

Medical Device	Germany
Specific provisions	According to MDR
Emergency situation without prior consent of patient or proxy - Studies allowed	
Conditions allowing trial participation in emergency setting without prior consent	According to MDR
Legal framework / Reference (Emergency Situation)	
Pregnant or breastfeeding women - Studies allowed	Yes Special provisions apply
Specific provisions	
Legal framework / Reference (Pregnant or breastfeeding women)	According to MDR
National legal framework for protection of vulnerable populations in place	
Applicable legal framework / Reference (Vulnerable Population)	
Guidelines & conventions for protection of vulnerable populations	
Additional Information	
Study participants - compensation & reimbursement	
Reimbursement for study participants	Optional
Compensation is limited to/provided for	Expenses arising from study participation (e.g. Travel)
Additional Information	Compensation fees for subjects (patients or healthy volunteers) participating in clinical investigations of MD (interventional, observational, combination studies, registries):"Aufwandsentschädigung" or travel costs.
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	No
Approval/authorisation required	No

Medical Device	Germany
Specific notification timelines before operations start	N/A
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	N/A
Contact name 2	N/A
Contact name 3	N/A
Phone	N/A
Fax	N/A
E-mail	N/A
Web address	N/A
Address	N/A
ZIP/City	N/A
Country	N/A
Additional information	
Archiving & data management	
Study documents must be kept at least (in years)	N/A
National legal framework in place	N/A
Applicable national legal framework/reference	N/A
Additional information	N/A
National Legislations	
General Information	
Official website providing relevant national legislation available	Yes
Official website providing relevant national legislation	Federal Institute for Drugs and Medical Devices/ Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM): Section: Medizinprodukte > Regulatorischer Rahmen >Gesetze und Verordnungen
Official governmental legal database available	Yes

Medical Device	Germany
Official governmental legal database	Juris BMJ: Free database of the Federal Ministry of Justice covering most of the German federal law
Additional information	
Investigations on Medical Devices	
Applicable national regulations	MPDG
Act on Medical Devices (or comparable national legal framework)	MPDG
Transposition of Directive 90/385/EEC	
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)	
Additional Information	
Combination studies (IMP/MD)	
Applicable national regulations	N/A
Legal act applicable to both study types	N/A
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	Radiation Protection law / Strahlenschutz-Gesetz (StrSchG)
Additional information	
Biobanking	
Specific framework available	N/A
Applicable legal framework	N/A
Additional information	N/A
Data protection	

Medical Device	Germany
Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)	Gesundheitsdatennutzungs-Gesetz (GDNG)
National DP act	Gesundheitsdatennutzungs-Gesetz (GDNG) GDPR
Implementing decrees / ordinances	
Other applicable regulations (covering DP related issues)	
Additional Information	
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	Yes
Applicable legal framework	BMGBGebV
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	
Investigation of MD - Definition available in national law	
MD Investigation - Definition	
Additional Information	

Medical Device	Germany
Further Definitions	
Additional information	N/A
Additional Information & Specifics	
Additional Information & Specifics Additional Information & Specifics	N/A