	DOCUMENTATION REGARDING THE APPLICATION FOR CLINICAL INVESTIGATION
▲	**Application form**
▲ (except for academic sponsor)	**Clinical evaluation plan** Summary of the clinical evaluation plan ☞ *precise Version number and Date*
▲	**Investigator's Brochure** (including annex if applicable) *Containing all items of annex XV chap II.2* ☞ *precise Version number and Date* **Or Instruction for use for CE medical device used within or without the scope of its intended purpose** ☞ *precise Version number and Date*
▲	**Clinical investigation Plan** *Containing all items of annex XV chap II.3* ☞ *precise Version number and Date*
▲ FR	**Protocol synopsis** ☞ *Summary of the clinical investigation plan including the objective(s) of the clinical investigation, the number and gender of subjects, criteria for subject selection, whether there are subjects under 18 years of age, design of the investigation such as controlled and/or randomized studies, planned dates of commencement and of completion of the clinical investigation*
	Other information *Please refer to Annex XV chap II 4*
▲	Signed statement by the natural or legal person responsible for the manufacture of the investigational device in question conforms to the general safety and performance requirements apart from the aspects covered by the clinical investigation and that, with regards to those aspects, every precaution has been taken to protect the health and safety of the subject
▲	Signed statement that the sponsor is aware that the competent authority may contact the ethics committee that is assessing or has assessed the application
▲ FR	Proof of insurance cover or indemnification of subjects in case of injury
▲ FR	Documents to be used to obtain informed consent, Patient Information form (including all written information to participants, payments and compensation of participants) Informed consent sheet Informed consent process
▲	Description of the arrangements to comply with the applicable rules on the protection and confidentiality of personal data/ personal information (refer to annex XV chap II 4.5)
O	Copy of the opinion of the Ethics Committee (CPP) or shall be submitted as soon as available
	Technical file
O	Statement of conformity: EC declaration of conformity or EU declaration of conformity (refer to art.19)
O	EC certificate
O	Instructions for use
O	Risk management documentation : Risk analysis report including results of risk analysis
O	List of standards and common specifications applied (if not included in the IB)
O	List of technical and functional features and the related expected clinical outcomes of the studied medical device
▲	Critical analysis of non-clinical and clinical data related to the MD studied in relation to the evaluation of the benefits and risks of the investigation
O	Pre-clinical data: (list not limited to)

Legend: ▲ = mandatory; O = if applicable ; FR = French language

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	• In particular regarding in- design calculations, in vitro tests, ex vivo tests, animal tests, mechanical or electrical tests, reliability tests, sterilization validation, stability tests, software verification and validation, performance tests, evaluation of biocompatibility and biological safety, as applicable • Detailed summary of preclinical data • Full reports of implantation tests (if applicable)
O	Clinical data : Detailed summary of clinical data
O	Summary of data justifying the use and safety of the EC marked MD outside the scope of its intended purpose
O	Dossier relating to the active substance if the MD incorporates as an integral part a substance likely to be considered as a medicinal product
O	New non-clinical and clinical data compared to previously submitted clinical investigation
O	Data on the viral safety of the MD
O	Data on radioelements
	Other documents – National requirements
▲ FR	Suitability of clinical investigators (CV) and suitability of investigational sites and investigational site team
O FR	Import certificate for investigational medicinal products used in the IC
O	Copy of the authorization issued by the third party to the sponsor to communicate the data related to the MD concerned and to use the IB and/or the technical file (as requested in the section 3.4 of the clinical investigation application form)
O	Expert panel opinion for class III and class IIb MD art 61.2
O FR	Implant card and information to be supplied to the patient with an implanted device
O	PMCF plan

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