ansm Agence nationale de sécurité du médicament et des produits de santé	**Annex 1 :** *Clinical investigation dossier – List of documents required by ANSM and CPP*

DOCUMENTATION REGARDING THE APPLICATION FOR CLINICAL INVESTIGATION	**1**	**1**	**2**	**2**	**3** **4.1** **4.2**	**4.3**	**4.4**
CE marked status	**Not CE marked**	**Outside destination CE**	**Not CE marked**	**Outside destination CE**	**CE marked**	**Outside destination CE**	**Not CE marked**
Class	**Classes I and IIa non invasive**		**Classes IIa invasive, IIb and III**		**All classes**	**All classes**	**All classes**
Application form (FAIC) - Please refer to annex 2 of AAP-part 2	▲	▲	▲	▲	▲	▲	▲
Clinical evaluation plan (CEP) The clinical evaluation plan ☞ *precise Version number and Date*	▲	▲	▲	▲	▲ **(except for 4.2 academic sponsor)**		
Investigator's Brochure (BI) (including annex if applicable) *Containing all items of annex XV chap II.2 (MDR)* and a list detailing the fulfilment of the relevant general safety and performance requirements set out in Annex I of MDR, including the standards and common specifications (CS) applied, in full or in part, as well as a description of the solutions for fulfilling the relevant general safety and performance requirements, in so far as those standards and CS have not or have only been partly fulfilled or are lacking. ☞ *precise Version number and Date* **The absence of IB should be justified (for example if the destination is similar but not covered by the CE certificate)* If the investigator's brochure belongs to a third party, the third party's authorization issued to the sponsor to use it should be submitted (**AUTORISATION_BI**) **Instruction for use (IFU) for CE medical device used within or without the scope of its intended purpose** ☞ *precise Version number and Date*	**IB**	**IB* + IFU**	**IB**	**IB* + IFU**	**IFU**	**IB* + IFU**	**IB**
Clinical investigation Plan (PROTOCOLE) *Containing all items of annex XV chap II.3 (MDR)* ☞ *precise Version number and Date*	▲	▲	▲	▲	▲	▲	▲
Protocol synopsis (RESUME) ☞ *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*	▲ **FR**	▲ **FR**	▲ **FR**	▲ **FR**	▲ **FR**	▲ **FR**	▲ **FR**

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CE marked status	**Not CE marked**	**Outside destination CE**	**Not CE marked**	**Outside destination CE**	**CE marked**	**Outside destination CE**	**Not CE marked**
Class	**Classes I and IIa non invasive**		**Classes IIa invasive, IIb and III**		**All classes**	**All classes**	**All classes**
Other information *Please refer to Annex XV chap II 4 (MDR)*							
Signed statement by the natural or legal person responsible for the manufacture of the investigational device in question that it 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 Please refer to annex 4 of AAP-part 2	▲	▲	▲	▲		▲	▲
Signed statement that the sponsor is aware that the competent authority may contact the ethics committee that is assessing or has assessed the application	▲	▲	▲	▲	▲	▲	▲
Proof of insurance **(ASSURANCE)** cover or indemnification of subjects in case of injury The proof of insurance cover must comply with the articles L. 1121-10 and R.1121-4 to R1121-9 of the French public health code. It must cover at least the period between the first inclusion and the last visit of a French participant. It must mention the estimated end date of the study and the contact details of the EU legal representative ** except for 4.1 and 4.2 with additional procedure not invasive, not burdensome*	▲ **FR**	▲ **FR**	▲ **FR**	▲ **FR**	▲* **FR**	▲ **FR**	▲ **FR**
Documents to be used to obtain informed consent **(NIFC),** Patient Information form (including all written information to participants, and compensation of participants) Informed consent sheet Informed consent process Please refer to page 7 of AAP-part 2 for details regarding the modalities of submission All the document used to recruit participants (letter to general practitioners, posters, explanatory booklets, websites, etc.) **(RECRUTEMENT)**	▲ **FR**	▲ **FR**	▲ **FR**	▲ **FR**	▲ **FR**	▲ **FR**	▲ **FR**
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) **(DONNEES)** Please refer to page 7 of AAP part 2 for details	▲	▲	▲	▲	▲	▲	▲
Copy of the opinion of the Ethics Committee (CPP) if available (to be submitted as soon as available) **(AVIS)**	O	O	O	O	O	O	O

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CE marked status	**not CE marked**	**Outside destination CE**	**not CE marked**	**Outside destination CE**	**CE marked**	**Outside destination CE**	**not CE marked**
Class	**Classes I and IIa non invasive**		**Classes IIa invasive, IIb and III**		**All classes**	**All classes**	**All classes**
Technical file (DOSSIER_TECHNIQUE)							
Statement of conformity: EC declaration of conformity or EU declaration of conformity (refer to art.19 MDR)		▲		▲	▲	▲	
EC certificate or for legacy devices, documents justifying the conditions of validity of the transitional period (refer to Regulation (EU) 2023/607 amending the transitional provisions (art 120) of Regulation (EU) 2017/745 on medical devices and to the FAQ published by the European Commission).		▲		▲	▲	▲	
Instructions for use of the studied MD for the clinical investigation *precise Version number and Date*	O	▲	O	▲	▲	▲	O
Risk management documentation : Risk analysis report including results of risk analysis for the clinical investigation	▲	▲	▲	▲		▲	▲
List of standards and common specifications applied (if not included in the IB)	▲	▲	▲	▲		▲	▲
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	▲	▲	▲	▲		▲	▲
Pre-clinical data: (list not limited to) • 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) • **The sponsor should submit all relevant data and all the available results at the date of submission in the initial dossier.**	▲	▲	▲	▲		▲	▲
Clinical data : Detailed summary of clinical data	▲	▲	▲	▲		▲	▲
Summary of data justifying the use and safety of the EC marked MD used outside the scope of its intended purpose		▲		▲		▲	
Dossier relating to the active substance if the MD incorporates as an integral part a substance likely to be considered as a medicinal product	▲	▲	▲	▲		▲	▲

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Class	**Classes I and IIa non invasive**		**Classes IIa invasive, IIb and III**		**All classes**	**All classes**	**All classes**
New non-clinical and clinical data compared to previously submitted clinical investigation	▲	▲	▲	▲		▲	▲
Data on the viral safety of the MD (if applicable) Please refer to annex 5 of AAP	▲		▲				▲
Data on radioelements (if applicable)	▲	▲	▲	▲		▲	▲
Other documents – National requirements (DOCUMENTS)							
Investigator list, proof of suitability of clinical investigators (LISTE_CV) and of suitability of investigational sites and investigational site team (EQUIPEMENT) Please refer to page 7 of AAP for details regarding the CV	▲	▲	▲	▲	▲	▲	▲
Authorisation of the investigational site (please refer to article L1121-13 of the French public health code) **(JUS_EQUIPEMENT)**	O	O	O	O	O for 4.2 with an invasive or burdensome additional procedure	O	O
Import certificate for investigational medicinal products used in the IC	O **FR**	O **FR**	O **FR**	O **FR**	O **FR**	O **FR**	O **FR**
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) **(AUTORISATION_BI)**	▲	▲	▲	▲		▲	▲
Expert panel opinion for class III and class IIb MD art 61.2 (MDR)			O	O		O	O
DSMB charter (**DSMB**)	O	O	O	O		O	O
Implant card and information to be supplied to the patient with an implanted device *except for legacy devices with an EC certificate extended till 2024 and for MD mentioned at art 18.3* (MDR)			O **FR**	O **FR**	O **FR**	O **FR**	O **FR**
PMCF plan	▲	▲	▲	▲	▲ except 4.2		
All other document **(DOCUMENT)**	O	O	O	O	O	O	O

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