DOCUMENTATION REGARDING THE APPLICATION FOR PERFORMANCE STUDY	1	1	2	2	3
CE marked status of IVD	**Not CE marked**	**CE marked and used outside the scope of its intended purpose**	**Not CE marked**	**CE marked and used outside the scope of its intended purpose**	**CE marked and used in its intended purpose**
Application form (FAEP) – Please refer to annex 2 of AAP-part 2	▲	▲	▲	▲	▲
Performance evaluation plan (PEP) Summary of the performance evaluation plan ☞ precise Version number and Date	O	O	O	O	O
Investigator's Brochure (BI) (including annex if applicable) Containing all items of annex XIV and a list detailing the fulfilment of the relevant general safety and performance requirements set out in Annex I of IVDR, 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	**BI**	**BI** [1] **+ IFU**	**BI**	**BI** [1] **+ IFU**	**IFU**
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 *in-vitro* medical device used within or without the scope of its intended purpose** ☞precise Version number and Date	O	O	O	O	O
Clinical Performance study Plan [CPSP] (PROTOCOLE) Containing all items of annex XIII (2 & 3) of IVDR ☞ *Precise Version number and Date*	▲	▲	▲	▲	▲
Protocol synopsis (RESUME) ☞ *Summary of the performance study plan including the objective(s) of the clinical performance study, 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 performance study.*	▲ **FR**	▲ **FR**	▲ **FR**	▲ **FR**	▲ **FR**

[1] The absence of BI should be justified (for example if the destination is similar but not covered by the CE certificate)

Legend : ▲ = mandatory ; O = if applicable ; FR = French language, **FILE NAME**

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CE marked status of IVD	**Not CE marked**	**CE marked and used outside the scope of its intended purpose**	**Not CE marked**	**CE marked and used outside the scope of its intended purpose**	**CE marked and used in its intended purpose**
Other information As applicable *Please refer to Annex XIV of IVDR*					
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 annex4 of AAP-part	▲	▲	▲	▲	NA (Not applicable
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	▲ **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	▲ **FR**	▲ **FR**	▲ **FR**	▲ **FR**	▲ **FR**
All the document used to recruit participants (letter to general practitioners, posters, explanatory booklets, websites, etc.) **(RECRUTEMENT)**	▲ **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 XIV chap I 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

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CE marked status of IVD	**Not CE marked**	**CE marked and used outside the scope of its intended purpose**	**Not CE marked**	**CE marked and used outside the scope of its intended purpose**	**CE marked and used in its intended purpose**
Technical file (DOSSIER_TECHNIQUE)					
Statement of conformity: *CE declaration of conformity or EU declaration of conformity (refer to art. 17 of IVDR)*	NA	▲	NA	▲	▲
EC certificate	NA	▲	NA	▲	▲
Instructions for use for performance study ☞ Precise Version number and Date	▲	▲	▲	▲	▲
Risk management documentation : Risk analysis report including results of risk analysis for the performance study	▲	▲	▲	▲	NA
List of standards and common specifications applied (if not included in the IB)	▲	▲	▲	▲	NA
List of technical and functional features and the related expected clinical outcomes of the studied *in vitro* diagnostic medical device	▲	▲	▲	▲	NA
Pre-clinical data The sponsor should submit all relevant data and all the available results at the date of submission in the initial dossier.	▲	▲	▲	▲	NA
Clinical data :Detailed summary of clinical data	▲	▲	▲	▲	NA
Summary of data justifying the use and safety of the EC marked IVD outside the scope of its intended purpose		▲		▲	NA
New non-clinical and clinical data compared to previously submitted clinical investigation (if applicable)	▲	▲	▲	▲	NA
Data on radioelements (if applicable)	▲	▲	▲	▲	NA

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Autres documents – Exigences nationales (DOCUMENTS)					
Investigator list, proof of suitability of clinical investigators **(LISTE_CV)** and of suitability of investigational sites and investigational site team **(EQUIPEMENT)**	▲	▲	▲	▲	▲
Authorisation of the performance study site **(JUS_EQUIPEMENT)**	O	O	O	O	O
Import certificate for investigational medicinal products used in the performance study	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 IVD ? concerned and to use the IB and/or the technical file (as requested in the section 3.4 of performance study application form) **(AUTORISATION_BI)**	▲	▲	▲	▲	NA
Expert panel opinion	O	O	O	O	NA
DSMB charter (**DSMB**)	O	O	O	O	NA
PMPF plan	O	O	O	O	O
All Other documents **(DOCUMENT)**	O	O	O	O	O

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