Clinical investigation supporting documents

Appendix of documents to attach

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Document** | **Version/Date** *At time of NCA application* | **Version/date***At time of NCA authorisation / refusal* | **Summary of changes made** | **Amended as a result of NCA/REC assessment** |
| **0. Cover letter** [ ]  |  |  |  |[ ]
|  |  |  |  |  |
| **1. Application form** [ ]  |  |  |  |[ ]
|  |  |  |  |  |
| **2. Investigator’s Brochure** [ ]  |  |  |  |[ ]
| Information to be submitted preferably as a separate document   |  |  |  |  |
| * Instructions of the Manufacturer [ ]
 |  |  |  | [ ]   |
| * Example of labels [ ]
 |  |  |  | [ ]   |
| * Instructions of use [ ]
 |  |  |  | [ ]   |
| * List of general safety and performance requirements [ ]

and applicable standards  |  |  |  | [ ]   |
| * Summary of the benefit-risk analysis and the risk [ ]

 management |  |  |  | [ ]   |
| **3. Clinical investigation plan** [ ]  |  |  |  | [ ]  |
| Information to be submitted preferably as a separate document:  |  |  |  |  |
| * Summary of the clinical investigation plan [ ]

in Italian |  |  |  | [ ]  |
| * Clinical evaluation plan details/or references [ ]
 |  |  |  | [ ]  |
| **4. Other information** |
| 4.1 Declaration of the natural or legal person responsible for [ ]   the manufacturing of the investigational medical device  |  |  |  | [ ]   |
| 4.2 Copy of the opinion/single opinion of the ethics [ ]  committees or coordinating ethics committee concerned   |  |  |  |  [ ]  |
| 4.3 Proof of insurance cover or indemnification of subjects [ ]   |  |  |  | [ ]  |
| 4.4 Documents to be used to obtain the informed consent, including [ ]  the information sheet and the informed consent document in Italian  |  |  |  | [ ]  |
| 4.5 Description of the arrangements to comply with the applicable [ ]  rules on the protection and confidentiality of personal data/ personal information  |  |  |  | [ ]  |
| **5. Documents required according to national regulations** |
| 5.1 Proof of payment of the fee [ ]   |  |  |  | [ ]  |
| 5.2 Declaration in lieu of the Affidavit of the legal representative of the Sponsor [ ]    |  |  |  |  [ ]  |
| 5.3 Declaration in lieu of the Affidavit of the legal representative of the Responsible for the manufacture [ ]   |  |  |  | [ ]  |
| 5.4 Copy of the power of attorney, when applicable [ ]    |  |  |  | [ ]  |
| 5.5 Documents on the suitability of investigational sites [ ]   |  |  |  | [ ]  |
| 5.6 List of the clinical sites and Ethics Committees concerned [ ]  |  |  |  | [ ]  |
| **6. When applicable** |
| Opinion of experts panels [ ]  |  |  |  | [ ]  |
| CE certificates of Notified Bodies [ ]  |  |  |  | [ ]  |
| Decisions of the other Competent Authorities concerned [ ]   |  |  |  | [ ]  |
| PMCF plan [ ]  |  |  |  | [ ]  |
| Recruitment procedures and advertising materials [ ]  |  |  |  | [ ]  |
| Opinion of other Ethics Committees concerned [ ]  |  |  |  | [ ]  |