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 |  |  |  |  |