# *Investigator's Brochure (IB) template for Device XXX*

***Background for template:***

The purpose of the investigator's brochure (IB) is to provide the principal investigator(s) with sufficient safety or performance data from pre-clinical investigation(s) and/or clinical investigation(s) to justify human exposure to the investigational device specified in the clinical investigational protocol. The IB shall be updated throughout the course of the clinical investigation as significant new information becomes available. The principal investigator(s) shall acknowledge the receipt of the IB and all subsequent amendments and keep all information confidential.

***Document Reference Number:***

***Name of Investigational Device:***

***Sponsor Name:***

***Sponsor Address:***

***Version No:***

***Date***:

**Revision History**

| Version Number | Date |
|---|---|
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**Authorised company signatory– Company Name** **Date**

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## 1. *INTRODUCTION*

If the required information of the IB is provided in other documentation, such documents shall be referenced in the IB and shall be made available upon request.

Summary of the medical device and include identification of any features of design that are different from a previously similar marketed product (if relevant).

Summary of what the device does.

Limitations of current treatments if relevant.

## 2. *INVESTIGATIONAL DEVICE INFORMATION*

### 2.1 Summary of the literature and clinical evaluation

A summary description of the literature and clinical evaluation and risk analysis that supports the design and the intended use of the investigational device.

### 2.2 Statement regarding the regulatory classification of the device, if relevant.

A statement describing the regulatory classification of the investigational device.

**Sample text:**
The device has been classified as a Class X device under Council Directive 93/42/EEC on Medical Device and MED-DEV Guidance Document 2.4/1. Rev 8, June 2010.

### 2.3 General Description of the investigational Device

A general description of the device including a list of accessories, principles of operation and flow diagrams of major components, together with a brief description of other devices designed to be used in combination for the purpose of the investigation, if applicable.

Identification of any features of design that are different from a previously similar marketed product (if relevant).

### 2.4 Summary of manufacturing and validation processes if applicable

A summary of the manufacturing processes and related validation processes used for the manufacture of the investigative device.
Details of any new or previously untested features of the device including, where applicable function and principles of operation.

Summary of experience with any similar devices made by same manufacturer including length of time on market and a review of performance related problems,

### 2.5 Mechanism of Action

A description of the mechanism of action of the investigational device, along with any supporting scientific literature.

Clinical data on device in question or similar device, if available. Reference should be made as to how experience with previous device models has affected the current iterations of design, if applicable.

Design drawings, if necessary for the understanding of the functioning of the device.

### 2.6 Manufacturer's instructions

A description of the manufacturer's instructions for the installation and use of the investigational device, including any necessary storage and handling requirements, preparation for use and intended re-use (e.g. sterilisation). Any pre-use safety or performance checks and any precaution to be taken after use (e.g.) disposal, if relevant.

Identification of any special manufacturing conditions required and if so, how such requirements have been met.

Method of sterilisation and validation (method, justification, if ETO-residuals) (if applicable) and methods of cleaning, disinfection and sterilisation for reusable devices.

### 2.7 Description of Intended Clinical performance

A description of the intended clinical performance as claimed by the manufacturer e.g. in what indications, etc.

Instructions for use/labelling including risks, contra indications and warnings (if available).

## *3. PRECLINICAL TESTING*

### 3.1. Summary

Describe the preclinical testing that has been performed on the investigational device, together with an evaluation of the results of such testing to justify it's use in humans. The summary will include or where appropriate refer to the results of:

**Design calculations**

Description of any calculations that were carried out in the designing of the investigative device

**In-vitro tests**

Description and results of any in-vitro tests that were carried out with the investigative device

**Mechanical and Electrical tests**
A description and a synopsis of any mechanical or electrical tests that were carried out on the investigational device.

**Reliability tests**
A description and synopsis of any of the reliability tests carried out on the investigative device.

**Validation of software relating to the function of the device**
A description and results of any validation carried out on software function of the investigative device.

**Performance tests**
A description and results of any performance tests carried out on the investigative device.

**Ex vivo Tests**
A description and results of any ex-vivo tests carried out on the investigative device.

**An evaluation of biological safety**
An evaluation of the biological safety of the investigative device as per ISO 10993.

Description of materials coming into contact with the body, rationale for choice of materials and which Standards apply (if relevant).

Description of how biocompatibility and biological safety have been addressed including identification of the risks and hazards associated with the use the device and how these have been addressed

Identification of any pharmacological components of device with description of intended purpose and previous experience with the use this substance

## ***4. EXISTING CLINICAL DATA***

**4.1. Summary of Clinical Experience**
Provide a summary of the relevant previous clinical experience with the investigational device and with medical devices that have similar characteristics, including such characteristics that relate to other indications for use of the investigational device.

**4.2Adverse Device Effects**
Provide an analysis of adverse device effects and any history of modification or recall.
Provide a list of expected adverse events and adverse device effects.

## *5. RISK MANAGEMENT*

**5.1 Summary of the risk analysis**
A description summary of the results of the risk analysis carried out on the investigative device, may be worth referencing the complete risk analysis report, if included e.g. as an appendix of the Clinical Investigation Plan (CIP)

Benefit/Risk analysis to include identification of hazards and estimated risks associated with the manufacture (including factors relating to device choice, choice of materials, software) and the use of the device, together with the description of what actions have been taken to minimise or eliminate the identified risks.

**5.2 Results of the risk assessment**
Describe the process and results of the risk assessment for the investigative device.

**5.3 Anticipated risks, contra-indications, warnings**
Describe any anticipated risks, contra-indications and warnings that are associated with the investigative device.

## *6. REGULATORY AND OTHER REFERENCES*

List of relevant Standards applied in full or in part, or description of solutions adapted to meet the essential requirements of the Directive if relevant standards have not been fully applied.

**6.1 List of International standards**

List the international standards complied with in full or in part e.g. ISO 14155, ISO 14971, ISO 13485

**6.2 Statement of conformity with national regulations**

Include a statement of conformity with the National regulations

**6.3 List of references**

List of references utilised in this document.