Template for submission of an interventional clinical study with MD (EN)

(Law nº21/2014, april 16th)

### EUDAMED number (if applicable): Date

### Note: EUDAMED number not applicable for PMCF

### 

### 1. Clinical Study identification

# 1.1 Sponsor:

1.1.1 Name:

# 1.2. Study Identification:

1.2.1 Reference:

1.2.2. Additional information:

# 1.3. Responsible (physician or authorised technician):

1.3.1. Name:

1.3.2. Medical area:

1.3.3. ID Professional card:

1.3.4. Institution(s) where clinical activity take place (hospitals, health clínics, etc.):

### 2. Clinical Study characterisation

#### 2.1. Starting date: \_\_\_\_\_\_\_\_\_ 2.2. Conclusion end: \_\_\_\_\_\_\_\_\_2.3. Expected duration: \_\_\_\_\_\_\_

2.4. Fill with a cross (X) in the gray fields the options that apply to this study:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| National |  | Internacional |  | Multicenter |  |

2.5. Countries enrolled:

2.6. Objetives e justification for the clinical study:

2.7. N.º of medical devices under investigation: \_\_\_\_\_\_\_\_\_\_\_\_\_

###### 2.8. Number of patients:

###### 2.8.1. Total:\_\_\_\_\_\_\_\_\_\_ 2.8.2. National: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2.9. Inclusion and exclusion criteria:

3. Institution(s) where the clinical study shall be performed

3.1. Name of the Institution:

3.2. Address:

3.3.Phone: 3.4.Fax:

3.5.Email:

# 3.6. Principal investigator:

3.6.1. Name:

3.6.2. Medical area/ Health Service:

3.6.3. ID Professional card:

### Note: If the study will be conducted in more than one institution the fields 3.1 to 3.6. should be duplicated

### 4. Medical device information

4.1. Identification of the medical device:

4.2. Tradename:

4.3. Classification of the medical device and justification

(Totally or partially applicable rules, according annex IX of Decree-law no. 145/2009 of 17 June, as amended, or article 3 v) of the same Decree-law)

4.4. EC Certificate N.º (if applicable): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

4.5. Notified Body (name and code) – if point 4.4. was filled: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### 4.6. Manufacturer or authorised EU representative :

4.6.1 Name:

4.6.2. Address:

4.6.3.Phone: 4.6.4. Fax:

4.6.5..Email:

4.7. Distributor

4.7.1 Name:

4.7.2. Address:

4.7.3.Phone: 4.7.4. Fax:

4.7.5..Email:

4.8 Brief description of the medical device (components, design, manufacturing methods, functioning):

4.9. Applicable Standards:

### 5. Information on other clinical studies with the same medical device

5.1. Have they been performed ?

## YES NO

5.2. In Portugal?

YES NO

5.3.In another country?

YES Which (give country name):

## 5.4. If the answer to the first question was YES, please complete the following data:

## 

## 5.4.1 Date: 5.4.2. Duration:

5.5. Objetives:

5.6. Conclusions:

Information or explanation:

For any queries on how to complete this “Template form for submission of a interventional clinical study with MD” please contact Health Products Directorate at INFARMED, I.P.:

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