**Sponsor statement on use of ICF MODEL for CLINICAL INVESTIGATIONS WITH A MEDICAL DEVICE ON ADULT PATIENTS**

[Intention of this template: The sponsor must add to the submission file a statement which describes which version of the ICF template was used, and (if applicable) which changes were made to the mandatory (purple) text of the template and for which reason. The following is a template for this statement. The color codes are used as described in the “MODEL ICF FOR CLINICAL INVESTIGATIONS WITH A MEDICAL DEVICE ON ADULT PATIENTS”.]

EU number: *Official EU CT number*

Trial number: *Sponsor trial number*

Sponsor(s) of the trial: *Name and address of the company, hospital, university or other organisation*

I, the undersigned representative of the sponsor in the member state, hereby confirm that for the above mentioned clinical trial application *(check where appropriate):*

[ ]  Informed consent forms are submitted and the Belgian ICF template for clinical investigation, version *click to enter version number*, publication date *click to enter date of publication* has been used,

[ ]  without changes to the mandatory text.

[ ]  with the following adaptations to the mandatory text, and because of the following reasons:

|  |  |
| --- | --- |
| Adaptation to section | Reason |
| E.g. I § 6.2. | E.g. to increase readability or fluency for the participant. |
| E.g. I § 10. | E.g. content was not applicable for the present trial |
|  |  |

[ ]  Informed consent forms are submitted and the Belgian ICF template for clinical investigation has not been used, because of the following reason: *click to enter text*

Surname and first name:

Date: DD/MMM/YYYY

Signature: