|  |  |  |
| --- | --- | --- |
|  | **FORM : EXTERNAL SPONSOR’S DECLARATION FOR THE NO-FAULT INSURANCE** | |
| N° : AAHRPP-FORM-004 / REV  001 | | N° ENGLISH VERSION : 043 |

***"Please do take into account that this is a translation of the original French version validated in the Quality Management System (QMS) of Cliniques universitaires Saint-Luc through the software Ennov GED. Therefore in case of doubt, differences, inconsistency or discrepancy in this English version, the French version shall prevail"***

Certificate to be signed by the sponsor’s insurance company

*(in the absence of other certificate)*



The undersigned, ,

insurance company covering the liability of the company ,

sponsor of the clinical research entitled:

…………………………………………………………………………………………………

…………………………………………………………………………………………………

………………………………………………………………………………………………… Protocol n° :

EudraCT N°:

Cliniques universitaires Saint-Luc Ethics Committee reference number : Certifies that:

1. The risk arising from such an experiment is covered according to article 29 of the Belgian law concerning experiments on the human person dated May 7, 2004 which requires from the sponsor :
   * to be liable even if faultless for the damage which the subject or, in the case of death, his rightful claimants sustained and which shows either a direct or an indirect connection with the experiments
   * before commencing the experiment, to enter into an insurance contract which covers this liability, and the liability of every individual intervening in the experiment, irrespective of the nature of the affiliation between the intervening individual, the sponsor and the subject.
2. Amounts insured are €

(specify the global and the individual amount).

1. The insurance cover is guaranteed during the experiment and for …. years after.

Signature: Date: