|  |  |
| --- | --- |
|  | **FORM – Insurance – External sponsor declaration form** |
| N° : AAHRPP-FORM-004 / REV  002 | 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 SharePoint PaCo 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 a certificate)*

The undersigned, ........................................................................................................................

insurance company covering the liability of the company ........................................................,

sponsor of the clinical study entitled :

.................................................................................................................................................................................................................................................................................................................................................................

Protocol n° :

EudraCT N° :

Internal reference of the Hospital Ethics Committee of the Cliniques universitaires

Saint-Luc :

attests that:

1. The risk resulting from this experimentation is covered in accordance with art. 29 of the Belgian law of May 7, 2004 relating to experiments on the human person and art. 32 of the law of December 22, 2020 relating to medical devices which impose on the sponsor :

* to assume, even without fault, the responsibility for the damage caused to the participant or his beneficiaries, damage directly or indirectly linked to the experimentation,
* to take out insurance prior to the experimentation to cover this liability as well as that of any person involved in the experimentation, regardless of the nature of the relationship between the person involved, the sponsor and the participant.

1. The amounts insured are set at ....................€ *(specify the global and individual amount)*.
2. The insurance coverage is guaranteed for the duration of the clinical experiment and for ............. years following the experiment.

Signature:

Date: