

Annex VII

Certificate of site / organization representative for low-intervention clinical trials Model

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Mr/Ms <<NAME OF REPRESENTATIVE OF SITE/ORGANIZATION>>, on behalf of <<NAME OF SITE/ORGANIZATION>>, with Tax ID Number <<Tax ID Number>>, and business address at <<ADDRESS OF SITE>>, by means of the present document.

HEREBY CERTIFIES:

1. The Site/Organization <<NAME OF SITE/ORGANIZATION>> has contracted a Professional Civil Liability Insurance Policy with the Company <<NAME OF COMPANY>>, No <<POLICY Number>>, in effect and up to date in payments, in order to cover the damages that may be suffered by a subject as a result of the health care activity performed by the Site/Organization,

2. The aforementioned policy covers the low-intervention clinical trial that, in accordance with Royal Decree 1090/2015, of 4 December, regulating clinical trials with medicinal products, Ethics Committees for research with medicinal products and the Spanish Clinical Studies Registry, are those clinical trials meeting the following conditions:

1. The investigational medicinal products, excluding placebos, are authorized.

2. According to the protocol of the clinical trial: 1. The investigational medicinal products are used in accordance with the terms of the marketing authorization, or 2. Use of the investigational medicinal products is evidence-based and supported by published scientific evidence on the safety and efficacy of those investigational medicinal products in any of the Member States concerned.

3. The additional diagnostic or monitoring procedures do not pose more than minimal additional risk or burden to the safety of the subjects compared to normal clinical practice in any Member State concerned.

3. The aforementioned policy or similar shall be kept in effect throughout the duration of the clinical trial.

Witnessed and for all relevant purposes, the present certificate is issued in <<City>> a <<Day>> of <<Month>> of <<Year>>

Signed: <<NAME>>