Form with Declaration of compliance with the requirements for admissibility of the optimized regulatory trust analysis procedure *(Reliance),* as per RDC No. 945/2024 and IN No. 338/2024.

1) Petitions subject to analysis by the optimized procedure

I. (__) Approval in the Process of the Clinical Development Dossier of Medication (DDCM), File No. _____ *(inform the DDCM file number).*

II. (__) Clinical Research Process Consent (DEEC), File No. _____ *(provide the DEEC file number).*

III. (__) Substantial modification to the product under investigation, File No. _____ *(provide the file number of the modification request).*

IV. (__) Substantial amendment to Clinical Protocol, Record No. _____ *(inform the number of the (file of the amendment petition).*

2) AREEs and documents subject to the optimized analysis procedure

In compliance with the provisions of Art. 42 of RDC No. 945/2024 and Art. 5 of IN No. 338/2024,
I DECLARE that:

a) The Active Pharmaceutical Ingredient (API) Dossier _____ *[inform the name or code of the API]* and the Investigational Product (DPI) or IMPD, version _____ *[inform the version]* linkedto the DDCM petition informed in "subparagraph I", of "item 1" or in the petition for Substantial Modification to the product under investigation informed in "subparagraph III", of "item 1", referring to the investigational drug _____ *[inform the name/code of the drug],* was approved by the Equivalent Foreign Regulatory Authority (AREE) _____ [inform *the name of the AREE]* of _____ [inform *the name of the country].*

b) The manufacturing process of the API and the product under investigation approved by AREE complied with the guidelines and principles described in the current ICH guides_____[inform *the number of the guides, when applicable],* according to the clinical development phase.

c) The clinical protocol, code/version _____ *[inform the code and version]* linked to the DEEC petition informed in "item II", of "item 1" or in the petition for amendment to the clinical protocol informed in "item IV", of "item 1" was approved by the Equivalent Foreign Regulatory Authority (AREE) _____[inform *the name of the AREE]* of_____[inform *the name of the country].*

I assume full civil and criminal responsibility for the information provided here.

_____ _____

Legal Representative of the Sponsor Technical manager