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BOLOGNA, August 13th, 2026

SUBSTITUTIVE DECLARATION OF CERTIFICATION AND NOTORIETY
(Made pursuant to Articles 46 and 47 of Presidential Decree No. 445 of December 28th, 2000)

The undersigned **DARIO DRAGA'**
born in **BRIXEN/BRESSANONE** on **February 2nd, 1964** and residing in **BOLOGNA** at **VIA BELLOMBRA, 5** (postal code **40136**), Tax Code **DRGDRA64B23B160I**,
aware of the criminal penalties referred to in Article 76 of Presidential Decree 445/2000 in the case of false declarations and the production or use of false documents,

DECLARES UNDER HIS OWN RESPONSIBILITY

1. Educational Qualification Requirement (Article 4, paragraph 1, letter a of the Ministerial Decree of November 15th, 2011):

That he holds the following Degree under the Old University System ("Vecchio Ordinamento") in health or scientific disciplines: **DOCTOR OF PHARMACY** obtained at the **University of BOLOGNA** on **February 8th, 1994**.

2. Theoretical Training Requirement (Article 4, paragraph 1, letter b of the Ministerial Decree of November 15th, 2011):

That he has successfully attended, within the 12 months preceding the start of monitoring activities, a theoretical training course with a total duration not less than 40 hours, covering the following topics:

- Methodology and regulations of clinical trials;
- Good Clinical Practice (GCP) guidelines;
- Good Manufacturing Practice (GMP) standards, with specific reference to the investigational drug;
- Pharmacovigilance;
- Quality systems and quality assurance;
- Duties of the clinical monitor (as provided for in paragraph 5.18 of Annex 1 to the Ministerial Decree of July 15th, 1997, as amended).

3. Practical Experience and Mentorship Requirement (Article 4, paragraph 2 of the Ministerial Decree of November 15th, 2011):

That he is qualified as "Expert CRA" (already in possession of the legal requirements), as by paragraph 5.18 of Annex 1 to the Ministerial Decree of July 15th, 1997.

- **4. Ongoing Annual Continuing Education (Article 4, paragraph 3 of the Ministerial Decree of November 15th, 2011):**

That he has fulfilled the ongoing annual continuing education requirements for year **2025**, having attended training/refresher courses of no less than 30 hours in subjects relevant to clinical research and GCP and performed at least 15 on-site visits.

Signature of the Declarant *Dakir Dhaga'* 13/08/2026