Letterhead of the Foreign Entity

Sample Declaration of the Legal Representative

| The undersigned | born in | on |
|--|-----------------|---|
| resident in(Country |)Street | No |
| Email/Pec (Certified Email) | | |
| In my capacity as the Legal Representati with its registered office in | (for on October | reign country indicated by the decision |

With reference to the request for inclusion in the LEEF

Considering the Agreement between the Government, Regions, and Autonomous Provinces of Trento and Bolzano dated February 2, 2017, regarding the document "Continuous Training in the Healthcare Sector," and in particular, letter c of paragraph 1 of Article 8, which stipulates that the National Commission for Continuous Training approves the Manual on the continuous training of healthcare professionals, following the mandatory and binding opinion of the Technical Committee of the Regions, approves the Manuals on the continuous training of healthcare professionals and provider verification, as heard by the Technical Committee of the Regions;

Considering the Determination issued by the National Commission for Continuous Training regarding the "accreditation process for training activities conducted within the European Community or abroad" on November 12, 2010;

Considering Article 39 of the State-Regions Agreement of February 2, 2017, which establishes that, for the purpose of fulfilling the training obligation, the completion of training activities outside the national territory may be recognized, and that the types of training activities and the procedures for recognizing credits earned outside the national territory are determined by the National Accreditation Manual for the delivery of CME events and the Manual on the continuous training of healthcare professionals;

Taking into account the Manual on the continuous training of healthcare professionals, approved by the National Commission for Continuous Training on October 25, 2018, and effective as of January 1, 2019, which, in section 3.4, regulates "Individual Training Abroad";

Acknowledging the founding resolution of the LEEF list adopted by the National Commission for Continuous Training on April 22, 2021.

Aware that the data provided with the request for inclusion in the LEEF constitutes a formal declaration of meeting the requirements and acceptance of the rules governing the CME system, without prejudice to all applicable legal provisions;

Aware of the sanctions stipulated in Article 76 of the Consolidated Text, Presidential Decree of December 28, 2000, No. 445, and of the loss of benefits as provided in Article 75 of the same Consolidated Text in the event of false or misleading statements, under one's personal responsibility;

DECLARES

| that the Foreign Entity | /(name) |): |
|-------------------------|---------|----|
|-------------------------|---------|----|

- has its main headquarters in(Countries indicated by the CNFC decision of the National Commission for Continuous Training on October 25, 2018);
- is internationally recognized;
- has as its institutional purpose training, research, or the provision of healthcare services;
- does not produce, market, distribute, or advertise healthcare products, and such activities are not carried out even indirectly;
- is not accredited in the Italian system as an ECM provider.

UNDERTAKES

- to ensure the existence of management procedures that govern the entire accreditation process of the training activity in its various phases;
- to verify the actual participation of healthcare professionals in the delivered events;
- to assess the perceived quality by participants in relation to the activities organized/delivered by the provider, as well as the perception of conflicts of interest influence in the CME event/material, regardless of the presence of sponsors;
- to evaluate, for the purposes of awarding training credits, the participants' learning at the end of the activities organized/delivered by the provider, using tools consistent with the stated objectives; to issue or send, including through electronic means, a specific credit acquisition certificate to the participants, following the verification to make all documentation accessible and facilitate meetings and other control activities;
- to communicate all additional data that may be requested by the accrediting body, including as a result of the revision of the contents in the National Accreditation Manual for the delivery of CME events;
- to inform the accrediting body of any changes in name, legal status, statutes, including the formation of consortia, etc., as well as any changes in the facts, states, and personal qualities declared above, in relation to new events related to the organization and management of the

Foreign Entity;

 to ensure the absence of influence by companies that produce, distribute, market, and advertise healthcare products;

to comply with the regulations on CME and promptly adapt to any changes and additions, as well as any other decisions by the CNFC, which can be found on the official website ape.agenas.it in the notices/communications section..

| Yours faithfully, | |
|-------------------|--------------------------|
| | the Legal Representative |
| | |
| Date | |