



**LETTER OF INTENT BETWEEN THE INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE IN THE MEDICAL TECHNOLOGY SECTOR, THE AMERICAN NATIONAL STANDARDS INSTITUTE, THE UNITED STATES AGENCY FOR INTERNATIONAL DEVELOPMENT AND THE SECRETARIAT OF HEALTH OF THE MEXICAN UNITED STATES, THROUGH THE FEDERAL COMMISSION FOR PROTECTION FROM SANITARY RISKS OF THE MEXICAN UNITED STATES.**

The Federal Commission for Protection from Sanitary Risks (COFEPRIS) of the United Mexican States, the Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector, or IACRC-MTS, the American National Standards Institute (ANSI) and the United States Agency for International Development (USAID), hereinafter referred to as “the Participants”;

**ENCOURAGED** by the desire to strengthen existing relations between the people, governments, and institutions of the United States and Mexico;

**RECOGNIZING** the importance of public health for the development of our countries;

**CONSIDERING** that health is an essential component of well-being and development, which in turn are strategic axes that promote and strengthen partnerships;

**CONSCIOUS** of the importance of working together to address common health problems and public health issues of mutual concern; and of the desirability of establishing mechanisms that contribute to the development and strengthening of the bilateral cooperation framework, addressing global health emergencies in an expeditious manner, as well as the implementation of projects and activities that have an effective impact on the progress of the health sector, protecting public health from any health risk to which might be exposed;

The Participants declare their intention to:



## OBJECTIVE

Cooperate with each other within the framework of Medical Technologies, including Medical Devices and Digital Technologies for Health, with a view to encouraging and facilitating mutual contacts, exchanges of information, training and cooperation between their government agencies, health institutions, health professionals, specialists and private institutions.

Develop scientific and technical work and promote actions of common interest, and collaborate on regulatory strengthening where appropriate.

To promote the competitiveness of the Medical Technology industry, through the optimization of processes, practices and regulations, at the level of best practices and international standards, in accordance with the responsibilities of each Participant.

Promote regulatory convergence of Medical Devices, based on Good Regulatory Practices and the referencing of internationally recognized standards.

Disseminate technical, scientific and ethical knowledge that supports both industrial development and regulatory policy development, so that sectoral knowledge and analysis allow the learning and mastery of new technologies.

Establish arrangements for the implementation of specific projects aimed at promoting the use of International Standards for Medical Device Regulatory Purposes, through the exchange of information, training and training resources, including those cooperative activities that, for this purpose and under these modalities, correspond to the Medical Device Regulatory Convergence Project (MDRC) of the Standards Alliance COVID-19 by the United States Agency for International Development (“USAID”), administered by ANSI in conjunction with the IACRC-MTS and its members.



## **INFORMATION PROTECTION**

Each Participant seeks to respect each other's legislation, regulation, policies and organizational guidance regarding protection of the information which originates or is shared during the execution of the present instrument, and in that regard, should not broadcast either, in full or in part, the information which is susceptible to be classified as reserved or confidential derived of the cooperation activities under the present instrument, without prior consent in writing by the other Participant.

## **NON-BINDING**

The Participants specifically acknowledge that this Letter of Intent is not an obligation of funds, nor does it constitute a legally binding commitment by the Participants under international law or the law of the United Mexican States or the United States of America. This is not an International Agreement and does not lead to any right nor obligation in virtue of international law. The Participants are entering into this Letter of Intent while desiring to maintain their own separate and unique missions and mandates.

Nothing in this Letter of Intent should be construed as superseding or interfering in any way with any agreements or contracts entered into by any Participant, either prior to or subsequent to the signing of this Letter of Intent. This Letter of Intent is neither a binding agreement nor does it constitute a treaty or create any rights and obligations under international law or the laws of Mexico or the United States of America.

## **MODIFICATIONS**

Modification of the terms of this Letter of Intent, including extending the period of operation, may be made through a written amendment signed by each of the Participants.



This Letter of Intent becomes operative on the date of its signature and shall remain operative until either Participant expresses its wish to terminate it by written notice to the other Participant thirty (30) days in advance.

### **SOLUTION OF CONTROVERSIES**

In case of any differences derived from the interpretation or execution of the present instrument, will be solved through a mutual agreement of the Participants.

Signed in four originals in English and Spanish. In the case of any conflict between the two versions, the English version will prevail.

In Mexico City, Mexico on the 31<sup>st</sup> days of the month of August, 2021.

**FOR THE FEDERAL COMMISSION  
FOR PROTECTION FROM SANITARY  
RISKS**

**FOR THE INTER-AMERICAN  
COALITION FOR REGULATORY  
CONVERGENCE IN THE MEDICAL  
TECHNOLOGY SECTOR**

**Alejandro Ernesto Svarch Pérez**  
Federal Commissioner

**Sandra Ligia González Aguirre**  
Executive Secretary

In Washington D.C., United States, on the  
\_\_\_ days of the month of \_\_\_\_ 2021.

**FOR THE UNITED STATES AGENCY  
FOR INTERNATIONAL  
DEVELOPMENT**

**FOR THE AMERICAN NATIONAL  
STANDARDS INSTITUTE**

**Bruce Adams**

**Joseph Tretler Jr.**  
Vice-President



Mission Director