

e-IFU: Strategies to implement as general practice

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INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE

MEDICAL TECHNOLOGY SECTOR

ANNIVERSARY



e-IFU Working Group

Problem Statement

- Some countries in LATAM do not accept e-IFU, however, it is a trend adopted for many companies

Main Objective

Provide documents/position that support the strategies to advocate e-IFU adoption across the countries.

LATAM state of art

GROUP	COUNTRY CLASSIFICATION	COUNTRIES	STRATEGY
Group 1	Regulation indicates IFU must be physically with the product, it means a regulatory restriction to adopt e-IFU.	Colombia-IVD, México, Paraguay – MD, Peru	Advocacy for regulation change
Group 2	Regulation does not mention IFU release method, it generates uncertainty regarding e-IFU adoption	Argentina, Bolivia, Costa Rica, Dominican Rep., El Salvador, Guatemala, Honduras, Nicaragua, Panamá, Uruguay	Request an official position
Group 3	Despite regulation includes e-IFU option (Digital IFU), it is not explicit, or regulator do not accept to replace paper IFU by e-IFU	Colombia – MD Ecuador	Advocacy for clarifying interpretation of regulation
Group 4	Regulation accept e-IFU for some products, however it is considering the scope is not enough	Brazil Chile*	On hold – depend on need
Group 5	Regulation already accept e-IFU	Paraguay - IVD	Not applicable

---- Regulation draft included e-IFU. Awaiting for final regulation to reclassify them.

---- Countries classification under revision

* It is not a fully regulated country

General activities

	Activity	Estatus	2025									2026		
			May	Jun	Jul	Aug	Oct	Nov	Dec	Jan	Feb	Mar		
1	Compiling state of art	Completed												
2	Discussion position papers available	Completed												
3	Main concerns of Health Autorities	In progress												
3.1	Internet connection	Completed												
3.2	Users do not feel comfortable with e-IFU (Survey)	In progress												
3.3	IFU printed on demand	Completed												
3.4	Version control	Completed												
4	Position document to recommend e-IFU	In progress												
5	Consultation to Health Authorities countries group 2	Not started												
6	Define strategies for countries groups 1 & 3	Not started												

Survey:

Methodology	
Audience	Health Care professionals
Scope	Argentina & Colombia
Distribution strategy	Argentina: CAPRODI- ALAC (Released Aug-25) Colombia: ANDI (Pending release)
Data collection	1 -2 months
Type of questions	Intended to understand what are the preferences of HCP regarding IFU (paper vs. e-IFU).

- Lay user products excluded from survey.
- Survey already validated by HCPs into the companies.



THANK YOU

SANDRA LIGIA GONZÁLEZ

Executive Secretary

Sandra@interamericancoalition-medtech.org

LETICIA FONSECA

Deputy Executive Secretary

Executive Secretary Brazil

leticia@interamericancoalition-medtech.org

MARINA CARVALHO

GRP and Trade Lead

marina@interamericancoalition-medtech.org