



Easy
IFU

The IFU Shift: Why Going Digital Matters for the Continent

Monir El Azzouzi

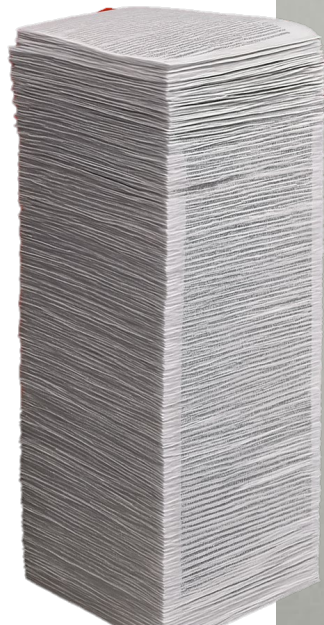


**Raise your hand if
you've actually read
the paper IFU before
using a product**



The Problem with Paper

- Lost Leaflets
- Outdated versions
- Micro-font
- Translation bottlenecks
- Environmental and cost burden



EU Eifu Framework

- EU Implementing Regulation 2021/2226
 - Defines when Eifu can replace paper
 - Risk Assessment
 - Paper on request
 - Version Control
 - Language access
 - Retention 10-15 years
- Amendment 2025/1234
 - Expands to more devices for professional use



IT'S NOT JUST EUROPE



- **Australia (TGA):** active guidance on supplying eIFU and expanding scope. Therapeutic Goods Administration (TGA)
- **Japan (PMDA):** electronic package inserts now the norm. (Pharma-led, but signals digital labeling maturity.)
- **APAC snapshot (GHWP):** multiple markets accept e-labeling in defined settings.
- **US FDA:** no single “eIFU regulation,” but e-labeling lives inside Part 801 + guidance ecosystem. (Practical translation: e-delivery must still meet labeling requirements.)

GUIDELINES ON REQUIREMENTS ON LABELLING OF MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTIC MEDICAL DEVICES

2024



**Guideline on
E-Labeling of Medical Leaflets of
Medicinal and Biological Products for Human
Use**

Year 2024

Code: EDREX: GL.BIOINN /CAP.Care. 001
Version No: 2
Issue Date: 01/05/2024
Effective date:05/2024

Mecomed Position Paper on Electronic Instruction for Use (E-IFU)

Introduction

In a period characterized by rapid digital transformation and technological advancements, the adoption of Electronic Instructions for Use (e-IFU) stands out as a critical evolution in the medical device sector. e-IFUs represent a significant leap towards enhanced efficiency, sustainability, and improved user experience. This position paper explores the integration of e-IFUs addressing the regulatory challenges and potential benefits as the industry moves towards digital solutions.

Executive Summary

This paper offers an overview of the Electronic Instructions for Use (e-IFU), highlighting the need for regulatory enhancement and industry collaboration. Representing the Medical Technology industry in the Middle East & Africa Region, Mecomed encourages the adoption of eIFU across various device platforms. Globally, eIFUs are embraced for their real-time updates, accessibility, and environmental benefits. Evidence from MedTech Europe supports a strong preference for e-IFU among healthcare professionals due to its ease of access and sustainability. The paper calls for collaborative efforts for higher adoption of E-IFU in the MEA Region and standardized implementation, ensuring security and accessibility to enhance healthcare delivery.

Global Adoption and Advantages of e-IFU

Electronic Instructions for Use (e-IFU) have been authorized for professional use across numerous countries globally, including the European Union (for selected product categories), Australia, the United States, Canada, Saudi Arabia, Bahrain, Turkey, the United Kingdom, Japan, Singapore, South Korea, and Brazil. This global acceptance highlights the crucial role e-IFU plays in ensuring that healthcare professionals, as well as lay users, have instant access to the most current instruction revisions, thus enhancing safety and efficacy by providing timely and accurate information.

Additionally, e-IFU facilitates a more straightforward process for users to search through content and quickly find necessary information. The shift towards flexible formats in patient information materials aligns with global trends, emphasizing the relevance and timeliness of adopting e-IFU systems.

IFUs provide to healthcare professionals and users, including:

- **Up-to-date information:** eIFUs available online ensure users have access to the most current information, including any important safety updates or several benefits recall information.
- **Increased availability:** eIFUs can be accessed via multiple platforms whenever the user needs them, which is especially important in a hospital environment where paper IFUs are likely to be disposed of or lost. Also, professional users have specific training in their medical discipline

Why eIFU Really Matters for Africa

- Accessibility for Remote and Multilingual Regions
- Bridging Infrastructure Gaps with Smart Alternatives
- Regulatory agility and Regional Harmonization
- Environmental and Economic Benefits
- Patient Safety and Real-Time Updates
- Data Traceability and Trust
- Inclusive Technology for Emerging Manufacturers

RISK MANAGEMENT

≠ RED TAPE;

**IT'S YOUR
SEATBELT**



Easy
IFU

Easy
Medical
Device

EU-Style Risk Assessment Elements



User Digital Access



Fallback in Emergencies



Website Resilience



Tamper Protection



Update Notifications



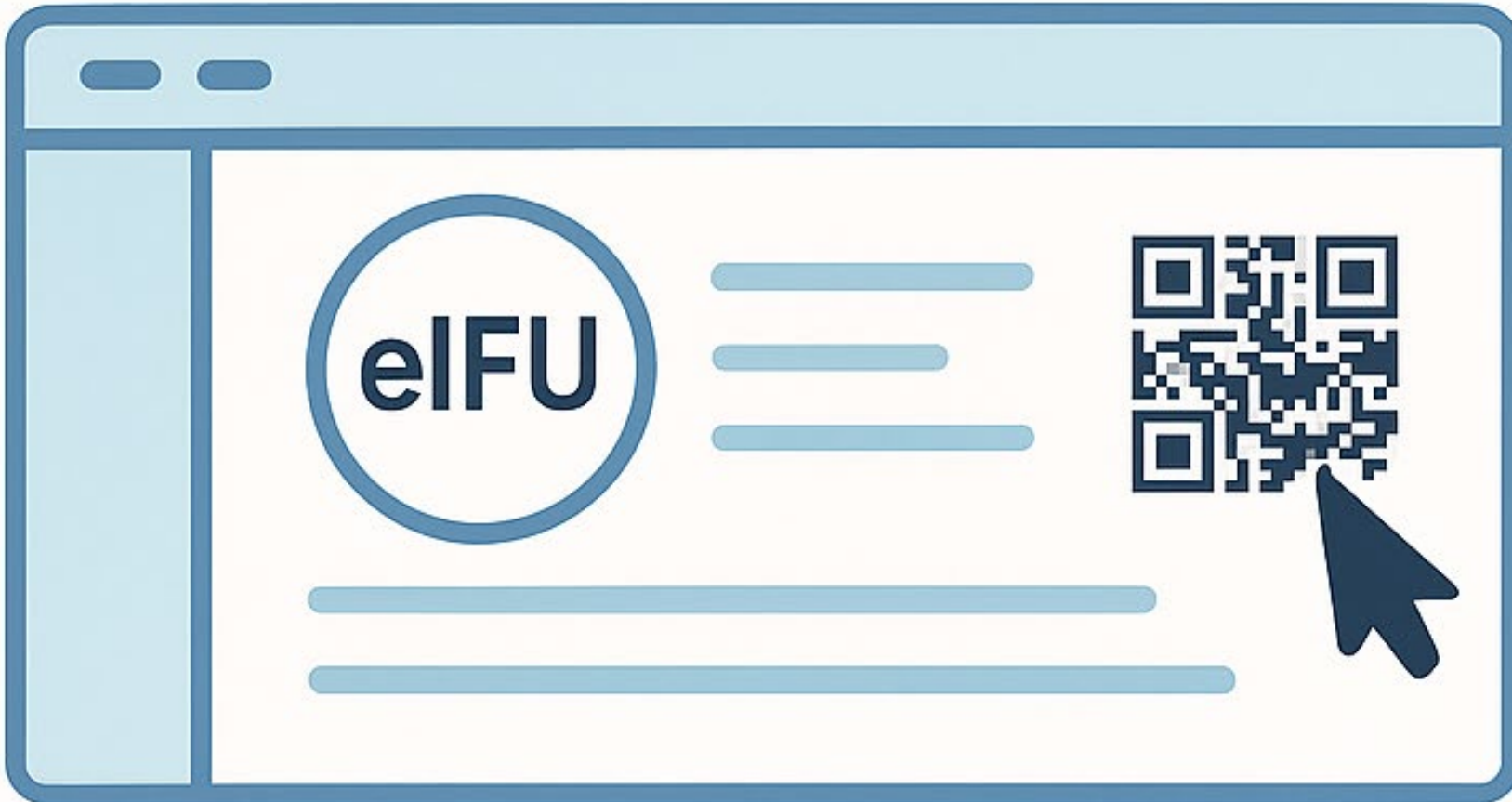
Language



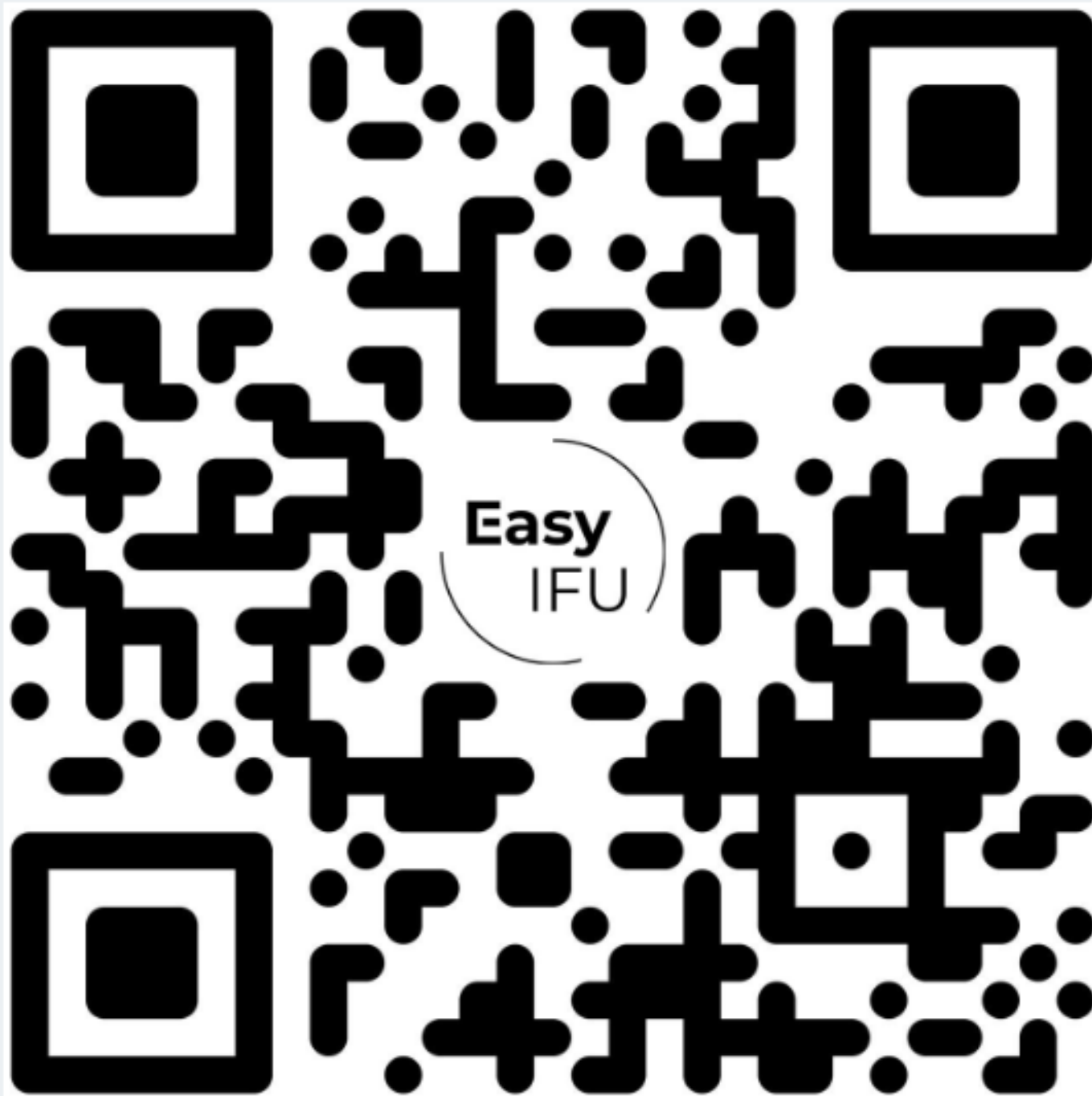
Should you invest on your own eIFU system?

EasyIFU.com

What “Good” Looks Like: A Platform Pattern




Easy
IFU



Scan me




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IFU



version:

select eIFU version by language:


- English
- French
- Global



version:

select eIFU version by language:

- English
 - Version 2.0
 - Version 1.0
- French
- Global




Easy eIFU
version: 2.0
language: English

select eIFU version by language:

- English
 - Version 2.0
 - Version 1.0
- French
- Global

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Instruction for Use V2

PRODUCT NAME
Model name

Description

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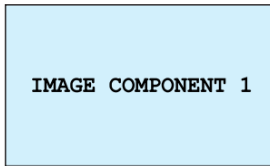
Intended use

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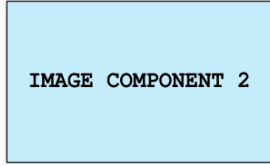
Components

- Component 1

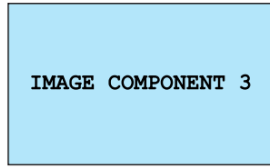
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- Component 2

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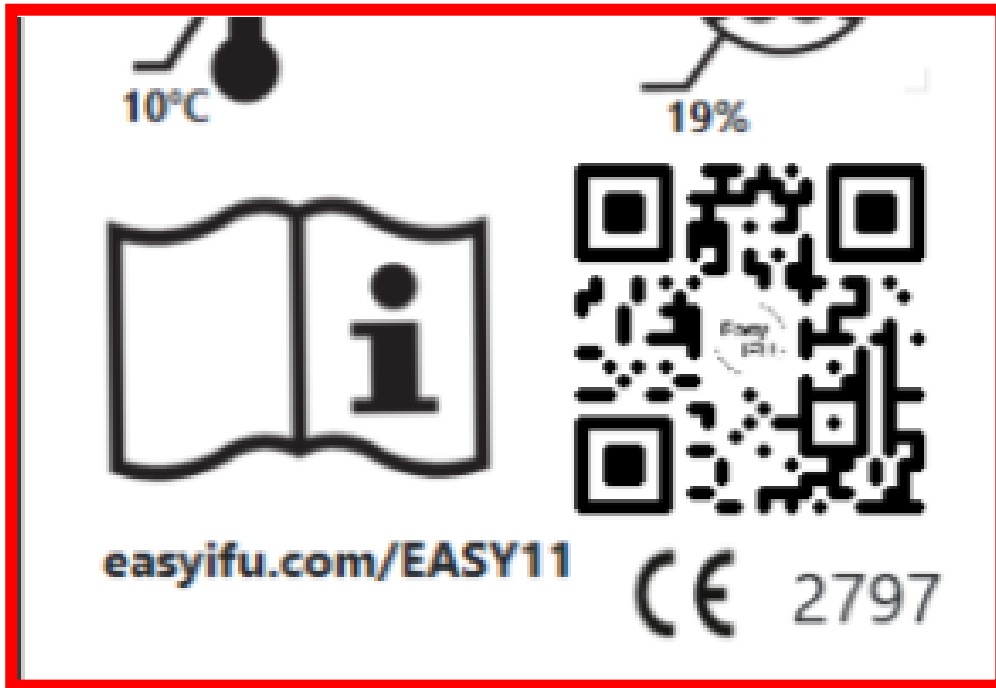

- Component 3

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Labeling

Answer questions and you'll get your label with the QR-Code and the URL for accessing the eIFU.



MD

EN-The device is intended for peripheral intravenous access for the administration of fluids, medication, or nutrients into the bloodstream.
FR-Le dispositif est destiné à l'accès intraveineux périphérique pour l'administration de fluides, de médicaments ou de nutriments dans la circulation sanguine.
NL-Het hulpmiddel is bedoeld voor perifere intraveneuze toegang voor het toedienen van vloeistoffen, medicijnen of voedingsstoffen in de bloedbaan.

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Next steps for EasyIFU

- **E-Labeling** – To simplify label and include more digitalization to help people understand the content.
- **AI to interrogate your IFU** – What if instead of searching the text within an eIFU you can ask your question.
- **Vocal IFU** – For people that have difficulty to read, we can ask the IFU to be read.
- **Video IFU** – Someone explains to you with a Video how to use your Device

**“Europe created the rules for digital IFUs.
Africa can turn them into real-life impact —
safer patients, smarter regulation, and a
greener continent.”**

**Easy
IFU**



T H A N K Y O U