FOR MANUFACTURERS ENTERING THE EU

Enter the EU market. Leave the paper behind.

Your Authorised Representative recommends Ydntfy for delivering your instructions for use electronically across the EU — always current, always available, in every language you need.

eIFU is now open to all professional-use devices

Implementing Regulation (EU) 2025/1234, in force since July 2025, extended eIFU to all medical devices intended for professional use, including Annex XVI products. If your devices qualify, the paper leaflet can stay out of the box.

RECOMMENDED BY YOUR AR

ENTERING THE EU MARKET

Why go electronic for the EU?

One market, 24 official languages, and users who now prefer their instructions electronic.* Paper multiplies that work; eIFU doesn't.

Always current in the field

Your customers open the approved, current version, never an outdated print. Updates and corrections go live across every member state in minutes, with a full audit trail.

Languages at scale

Each EU market can require its own language. A new market means uploading a file, not planning a print run, and every version stays aligned in one place.

Lighter packaging and logistics

No leaflet to insert, reprint or scrap. Packaging gets smaller, logistics get cheaper, and you support your Packaging & Packaging Waste Regulation (PPWR) goals.

Per-country usage data

See your IFUs being accessed per country: evidence of availability for compliance, and a market signal paper never gave you.

* Implementing Regulation (EU) 2025/1234, recital (2): a European Commission survey on replacing paper instructions for use with electronic ones (1 August – 10 October 2024) shows a clear preference among healthcare professionals for receiving instructions for use in electronic form rather than on paper.

COMPLIANCE BUILT IN

Compliant from day one in the EU.

The eIFU rules set conditions. The platform meets them for you.

The requirements, handled

Controlled access, version control, archiving of superseded versions, per-country language management and paper on request within seven days: the platform covers the conditions of Regulations (EU) 2021/2226 and 2025/1234.

Easier for you and your AR

Clean version history and controlled distribution make it simple to share current and superseded IFUs with your Authorised Representative, importers and competent authorities.

eIFU applies to devices intended for professional use; where lay use is reasonably foreseeable, paper remains required. Rules for IVDs differ. We'll help you assess which of your devices qualify. Our standard plans apply, published openly at ydntfy.com/en/pricing.

HOW IT WORKS

Three steps to paperless in the EU

1

We assess eligibility

A short review of your portfolio shows which devices qualify for eIFU under the EU rules.

2

You publish your IFU

All languages in one place, version-controlled, with superseded versions archived automatically.

3

Every user stays current

Users across the EU always open the latest version in their language, on any device.

Ready to leave paper behind?

Book a short introductory meeting. We'll walk you through the requirements, the steps and the pitfalls to avoid: no commitment, just a clear picture of what's possible for your products.

Learn more at ydntfy.com

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