Instructions for Use for Medical and In Vitro Diagnostic Device Regulations

Medical and in vitro diagnostic device manufacturers work every day to ensure the highest standards of safety and quality when producing their devices.
We're experts at ensuring our clients comply with regulatory requirements when creating and translating technical documentation, including Instructions for Use (IFUs).

MDR/IVDR Experts

Through our global partnerships, we've gained extensive experience creating and translating mono- and multilingual IFUs and are MDR and IVDR subject matter experts. We offer clients specialized services to ensure regulatory compliance and audit-ready technical documentation, including:

- Source File Analysis
- MDR or IVDR Compliance Check
- Management of In-Country Review (ICR)
- Summary of Safety and Clinical Performance (SSCP)
- IFU Analysis and Optimization
- Certificates of Accuracy

We don't just translate IFUs into all needed target languages; we optimized the entire IFU creation process. After performing an IFU audit, our analysis allows us to:

- Verify documents for product liability and safety risks
- Increase brand adherence
- Lower translation and printing budgets
- Improve user experience

We Help You Eliminate Risk

We know that creating high-quality, compliant technical documentation is a complex process. In addition to our ISO-certified translation capabilities for technical documentation, we have designed specific services that assist our clients with successful MDR and IVDR compliance, audit readiness, and reduced translation budgets.

A Customer Success Story

We worked with a leading medical device company to update its IFU repository and translate the documents into 20+ languages in preparation for MDR and IVDR compliance.

As part of our process, we:

- Verified MDR & IVDR Compliance
- Handled the In-Country Review Process for the Client
- Optimized the IFU Creation and Translation Process
- Created and Verified Terminology

As a result, our client realized cost-saving, efficiency, and quality benefits, including:

50%
Reduction In-Country Review Cycle Time

15%
Reduction in Translation Budget

Created a **Consistent** and **Professional** IFU aesthetic for enhanced global branding and improved user experience

Increase MDR Compliance and audit readiness by identifying missing IFU content

Up to **25%** Reduction in Translation & Printing Budgets by Shortening IFUs

Consistently Translated Target Languages through terminology harmonization

We Work With

20 of the **Top 20**
Medical and In Vitro Diagnostic Device Companies

We Are

ISO Certified
ISO 9001:2015, ISO 13485:2016, ISO 17100:2015, ISO 27001:2013, ISO 18587:2016

We Have

30+ Years Experience
with exclusive focus on life sciences

For further information, please visit: rws.com/medical-devices