The EU Medical Device Regulation and In Vitro Device Regulation

If you're like many medical and in vitro diagnostic device companies, the EU's Medical Device Regulation (MDR) and In Vitro Device Regulation (IVDR) have posed new complications and challenges. Under these regulations which are designed to ensure the highest possible safety and quality standards for medical and in vitro diagnostic devices in Europe, companies have a greater number of requirements to follow. You now need to provide more clinical evidence, ensure accuracy and availability of product documentation and labeling content in all 24 EU languages, follow stricter requirements for IFUs, and translate all operating manuals, marketing materials, patient information manuals, clinical performance information, interfaces for software products, and more. It's a lot to handle.

We can help.

At RWS, we've been working with clients to prepare for the new regulations for the past five years. We offer specialized, ISO-certified services to ensure MDR and IVDR compliance and audit-ready technical documentation, including:

- ✓ Source File Analysis
- ✓ MDR and IVDR Compliance Check
- ✓ IFU Optimization
- ✓ Certificates of Accuracy
- ✓ Management of In-Country Review (ICR)

Each of these specialized processes helps you get your product to market faster while reducing risk. When we translate IFUs, for example, we don't just provide a translation—we optimize the entire IFU creation process and verify compliance according to:

- ✓ Machinery Directive 2006/42/EG
- ✓ DIN EN 82079 Creation of User Manuals
- ✓ ANSI Z535, Presentation of Safety Instructions

The result for you?

- ✓ Reduced translation and printing costs
- ✓ Risk mitigation
- ✓ Better user experience
- ✓ More consistent global branding

RWS in Action

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

As part of our process, we:

- Verified MDR compliance
- Optimized the IFU creation and translation process
- Handled the in-country review process for the client
- Created and verified terminology

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

- ✓ Reduced in-country review cycle time by over 50%
- ✓ Reduced translation budgets by 15%
- ✓ Increased MDR compliance and audit readiness by identifying missing IFU content
- ✓ Reduced translation and printing budgets by shortening IFUs by up to 25%
- ✓ Consistently translated target languages through terminology harmonization
- ✓ Created a consistent and professional IFU aesthetic for enhanced global branding and improved user experience

You're in good company.

Some of the world's most innovative and trusted life sciences companies count on us as their trusted language and content partner. You could be next.

Serving 20 of the 20 top pharmaceutical companies.

1,400+ in-house linguists.

Helping 20 of the 20 top medical device companies.

24/7/365 support across the globe.

Working with 8 of the top 10 Contract Research Organizations.

Who is RWS

RWS is a world-leading provider of technology-enabled language, content management, and intellectual property services whose customers include the top 20 pharmaceutical companies worldwide. We help our customers to connect with and bring new ideas to people globally, by communicating business-critical content at scale and enabling the protection and realization of their innovations.

For further information, please visit: **www.rws.com**