Language solutions for IVDR submissions

Changes to European regulations are creating new and additional requirements for in-vitro diagnostic device companies to supply product documentation in multiple languages.

We offer a proven and trusted solution – supplying linguistic skill, a deep understanding of the industry, and highly specialized regulatory knowledge.

New regulations, new challenges

In-vitro diagnostic companies face a range of new challenges in the way they create, manage, translate, submit, and deliver content and technical documentation in order to meet all the In-Vitro Diagnostic Medical Device Regulation (IVDR) requirements – including additional documentation that must be presented and translated much earlier in the certification process.

According to the updated regulations, in-vitro diagnostic companies are required to:

- Provide more clinical evidence
- Ensure the accuracy and availability of product documentation and labelling content in potentially all 24 EU languages
- Follow stricter requirements for instructions for use (IFUs) and summary of safety and performance (SSPs)
- Translate all:
  - Operating manuals
  - Marketing materials
  - Patient information manuals
  - Clinical performance information
  - Interfaces for software products

Changes to the regulations mean that more devices now have to conform to the new rules, as well as many existing products having to be reclassified and recertified.

One of the key aims of the regulatory change is to improve device quality, safety, and reliability, while ensuring patient safety in an ever-developing market. To achieve this, in-vitro diagnostic device companies now need to provide content that is clear, accurate and understandable to all readers – both medical and non-medical professionals.

Ensure global compliance in all target markets

High-quality, compliant content is critical for your work at every stage of the product lifecycle – from research and development to production to patient engagement.

At RWS we understand the specific requirements and processes for regulatory content submission.

Our full range of solutions has been carefully designed to provide our in-vitro diagnostic (IVD) manufacturing partners with greater content control and oversight – helping them to achieve compliance in all target markets.

We are experts at ensuring our clients comply with regulatory requirements when creating, translating, and submitting content and technical documents, including:

- Instructions for use (IFUs)
- Operating manuals
- Patient information manuals
- Installation manuals
- Regulatory compliance documents
- Summary of safety and performance (SSPs)
- Summary of product characteristics (SmPC)

We can also assist with other translation needs such as:

- Manufacturing procedures
- Package inserts and labels
- Software applications
- Patents
- Data sheets
- Multilingual websites
- Marketing materials
- Legal and financial documents
- Customer communications

Translating content for in-vitro diagnostic device companies requires not just linguistic skill, but also a deep understanding of the industry and highly specialized regulatory knowledge.

IVDR solutions you can trust

We offer a range of content solutions to guide you through the complexities of the IVDR compliance journey and the creation of any audit-ready multilingual technical documentation that you are required to produce.

With IVDR compliance, there is a much sharper focus on IFUs and SSPs. We offer advice and support with improving them – ensuring they are clear, concise, compliant and relevant for the intended recipients prior to starting the translation phase.

IVDR compliance verification

We now offer IVDR compliance verification to ensure that your IFUs are 100% in alignment with the requirements of EU IVDR 2017/746. You receive a detailed report with non-conformities, highlighting the sections that need to be made compliant with the regulations.

IFU verification and optimization

We don't just translate IFUs into all required target languages – we optimize the entire IFU creation process. After performing an IFU audit, our analysis allows us to verify documents for product liability and safety risks – while lowering translation and printing costs, increasing brand consistency and improving the user experience.

Certificates of accuracy

Certificates of accuracy are supplied as part of our deliverables to help you with compliance and your internal audits.

Management of in-country review (ICR) and independent review and acceptance process (IRAP)

Our project managers oversee and coordinate in-country review (ICR) activities by the client or client's affiliate, ensuring all feedback and linguistic preferences are captured prior to finalization of the project. We can also provide an independent review and approval process (IRAP) to supply and coordinate with an independent linguistic reviewer for situations where the client does not have access to a qualified individual in the target language, or for administrative or timing reasons.

With our proven centralized content solutions, we can guide you through the complexities of the IVDR compliance journey – making sure the process is as efficient as possible.

Our content and linguistic offering includes:

- Translation and localization in over 330 languages
- Machine translation + post-editing
- Linguistic review
- Terminology and style guides
- Subtitling, voiceover (VO) and multimedia engineering
- Translation management system (TMS)
- Structured content authoring and management technology

Our specialized language solutions help you to:


Navigate the regulatory landscape


Guarantee greater brand consistency

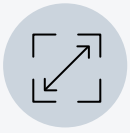

Gain greater process efficiency


Improve the user experience


Reduce translation costs


Achieve faster speed-to-market


Reduce risk


Address scalability

Why RWS?

We have a deep understanding of your world and the challenges you face.

For over 30 years we have been a trusted partner of medical and in-vitro device organizations, offering ISO-certified multilingual solutions and translation services in over 330 languages.

We work with the top 20 medical and in-vitro diagnostic device companies

Our expert translators:

- Hold advanced degrees in the sciences
- Are native speakers of the languages in which they work
- Are based in-country to ensure the most precise and nuanced translations
- Are tested, validated, and monitored to ensure they meet ISO 17100:2015 requirements and our ISO Quality Management System

ISO-certified translation process:

- ISO 9001:2015
- ISO 13485:2016
- ISO 17100:2015

In accordance with:

- IVDR 2017/746
- Machinery Directive 2006/42/EG
- DIN EN 82079 Creation of User Manuals
- ANSI Z535, Presentation of Safety Instructions

With our extensive experience in life sciences translation and industry regulations, we are the ideal partner to see you through the current and upcoming changes.

Our tried and tested methods will help you scale up your translation processes efficiently and ensure full compliance with all regulatory requirements – now and in the future.

Learn more

rws.com/medical-devices

About RWS

RWS Holdings plc is a unique, world-leading provider of technology-enabled language, content and intellectual property services. Through content transformation and multilingual data analysis, our unique combination of technology and cultural expertise helps our clients to grow by ensuring they are understood anywhere, in any language.

Our purpose is unlocking global understanding. By combining cultural understanding, client understanding and technical understanding, our services and technology assist our clients to acquire and retain customers, deliver engaging user experiences, maintain compliance and gain actionable insights into their data and content.

Our clients include 90 of the world's top 100 brands, the top 20 pharmaceutical companies and 19 of the top 20 patent filers. Our client base spans Europe, Asia Pacific, and North and South America. We work in the automotive, chemical, financial, legal, medical, pharmaceutical, technology and telecommunications sectors, which we serve from 80+ global locations across five continents.

Founded in 1958, RWS is headquartered in the UK and publicly listed on AIM, the London Stock Exchange regulated market (RWS.L).

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

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