

IVDR TRANSLATION GUIDE



Navigating Language Requirements for
In Vitro Diagnostic Medical Devices

WHO WE ARE

For over 25 years, Omnilingua has been the trusted translation partner for companies navigating the complex world of regulated industries. Our speciality? Transforming intricate medical, technical, and scientific documentation into flawless translations that meet the most stringent regulatory requirements.

Our secret weapon is our network of translators – not just linguists, but subject matter experts who work exclusively in their native language and specialised fields. This unique combination ensures exceptional accuracy in every translation we deliver.

We've embraced innovation without sacrificing quality, combining cutting-edge Translation Memory Software with Neural Machine Translation to deliver solutions that are faster and more cost-effective than traditional approaches.

With the IVDR creating new compliance challenges for IVD manufacturers, this guide will equip you with the critical insights needed to navigate the translation requirements successfully and ensure your path to European market access remains clear.



**TRANSLATING COMPLEXITY
WITH EXPERT PRECISION
FOR OVER 25 YEARS**

INTRODUCTION

The regulatory landscape for in vitro diagnostic medical devices has undergone a seismic shift. The In Vitro Diagnostic Medical Devices Regulation (IVDR EU 2017/746) isn't just an evolution of previous standards – it's a complete transformation that demands more comprehensive documentation, stricter classification criteria, and more rigorous conformity assessments.

At the heart of this challenge lies a critical but often underestimated component: translation. As your IVD products cross borders, so must your documentation – and not just any translation will do. Regulatory compliance demands precision, consistency, and cultural sensitivity that only specialised translation can deliver.

This guide cuts through the complexity of IVDR language requirements, offering clear, actionable insights to help manufacturers ensure their translations meet the necessary standards for successful market access. Whether you're navigating IVDR for the first time or adapting existing processes to the new regulation, you'll find practical guidance to streamline your compliance journey.



IVDR OVERVIEW: A TRANSLATION PERSPECTIVE

The IVDR doesn't mince words when it comes to language requirements. Article 10(10) states:

"Manufacturers shall ensure that the device is accompanied by the information set out in Section 20 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient."

This isn't just regulatory jargon – it's a clear mandate that places the responsibility squarely on manufacturers to provide information in the official languages of every EU Member State where you'll market your device. For UK manufacturers navigating the post-Brexit landscape, this creates a dual challenge of meeting both UK and EU requirements when selling across these markets.

**THIS ISN'T JUST
REGULATORY
JARGON – IT'S A
CLEAR MANDATE
THAT PLACES THE
RESPONSIBILITY
SQUARELY ON
MANUFACTURERS**



KEY TRANSLATION REQUIREMENTS FOR IVDR TECHNICAL DOCUMENTATION

① LABELLING AND INSTRUCTIONS FOR USE (IFU)

The IVDR doesn't leave room for interpretation. Annex II Section 2 demands:

- Labels on the device and its packaging (single unit, sales, transport) must speak the languages of your target markets
- Instructions for use must be available in all languages accepted in the Member States where you'll sell your device

This requirement spans your entire packaging hierarchy:

- Device labels that speak directly to users
- Primary packaging that protects your device
- Secondary packaging that houses your product
- Transport packaging that ensures safe delivery (where specific handling is required)

For UK companies eyeing both domestic and EU markets, this typically means preparing your English master content, then creating carefully translated versions for each EU country in your commercialisation plan.

② SUMMARY OF SAFETY AND PERFORMANCE (SSP)

Class C and D devices face an additional challenge: the Summary of Safety and Performance (SSP) required by Article 29. This critical document must:

- Communicate clearly to intended users
- Stand up to public scrutiny on EUDAMED
- Cover specific elements including device identification, intended purpose, warnings, and performance data

While you might initially draft your SSP in English, remember that final versions must be translated for your target markets – and since these documents will be publicly available, their quality directly impacts your brand perception.

3 TECHNICAL DOCUMENTATION TRANSLATION CONSIDERATIONS

The IVDR demands technical documentation that's "presented in a clear, organised, readily searchable and unambiguous manner." When translating this documentation, consider:

- Maintaining perfect terminology consistency across all documents
- Preserving the precise formatting and structure in every language
- Ensuring technical accuracy that leaves no room for misinterpretation
- Maintaining accurate cross-references between documents across languages

4 TRANSLATION REQUIREMENTS FOR DIFFERENT CLASSIFICATION CLASSES

Not all IVDs are created equal, and neither are their translation requirements:

- **Class A devices:** While documentation requirements may be less demanding, labelling and IFUs still require careful translation
- **Class B and C devices:** More extensive technical documentation means more translation needs
- **Class D devices:** The highest risk classification brings the most stringent requirements, including translation of specialised verification documentation

5 POST-MARKET SURVEILLANCE DOCUMENTATION

The regulatory relationship doesn't end after approval. Annex III of the IVDR requires ongoing post-market documentation:

- Post-market surveillance plans that outline your monitoring strategy
- Post-market surveillance reports for Class A and B devices
- Periodic Safety Update Reports (PSURs) for Class C and D devices
- Post-Market Performance Follow-Up (PMPF) documentation that tracks real-world performance

For Class C and D devices, PSURs must be updated at least annually and included in technical documentation. These updates may require translation for submission to competent authorities across different member states, creating an ongoing translation requirement throughout your product lifecycle.

BEST PRACTICES FOR IVDR TRANSLATION PROJECTS

1. Start With Clear Source Documentation

Before translation begins, ensure your English-language documentation is:

- Complete and finalised to prevent costly revision cycles
- Crystal clear with consistent terminology
- Free from ambiguities that could become magnified during translation

2. Create Comprehensive Terminology Databases

Building a strong terminology foundation pays dividends:

- Develop product-specific glossaries with approved translations
- Capture unique terms and phrases that define your technology
- Align regulatory terminology with IVDR requirements to ensure compliance

3. Implement Rigorous Quality Control

IVDR translations demand a multi-layered quality approach:

- Initial translation by specialists with IVD expertise
- Review by second translators who understand medical and diagnostic terminology
- Final verification by regulatory specialists who know what authorities expect
- Comprehensive consistency checks across your entire documentation ecosystem

4. Plan for Regulatory Updates

The IVDR landscape continues to evolve through:

- MDCG guidance documents that clarify requirements
- Common Specifications that set standards
- Updates to harmonised standards that influence compliance

Work with translation partners who actively monitor these changes and can update your translations accordingly.

5. Address UK/EU Regulatory Differences

For UK manufacturers targeting both domestic and EU markets:

- Map the growing differences between UK and EU regulatory frameworks
- Consider creating market-specific documentation versions where necessary
- Stay alert to diverging requirements as regulations evolve post-Brexit

COMMON TRANSLATION CHALLENGES IN IVDR DOCUMENTATION

1 TECHNICAL TERMINOLOGY CONSISTENCY

Maintaining consistent translation of technical terms isn't just about quality – it's about safety:

- Inconsistencies can confuse users and potentially impact test results
- Regulatory authorities may question documentation with terminology variations
- Safety information with inconsistent terms creates unnecessary risks

2 FORMATTING AND LAYOUT PRESERVATION

Technical documentation often contains complex elements that must be precisely maintained:

- Tables and charts that present critical data
- Cross-references that guide users through complex information
- Numbering systems that organise related content

These elements must be faithfully preserved across all languages while maintaining readability.

3 MANAGING DOCUMENT UPDATES

IVDR documentation isn't static – it evolves throughout your product lifecycle:

- Product specification changes may trigger documentation updates
- Risk assessments evolve as new information emerges
- Post-market surveillance generates new data
- Regulatory requirements continue to develop

Each update cascades through all translations, requiring sophisticated version control systems to maintain compliance across languages.

CONCLUSION

In the complex world of IVDR compliance, translation isn't just a box to tick – it's a critical component of successful market access. By understanding the specific language requirements and establishing robust translation processes, manufacturers can navigate IVDR compliance more effectively while ensuring their products reach all intended markets.

Partnering with translation specialists who understand both IVDR requirements and the technical complexities of in vitro diagnostic devices provides a critical advantage in this challenging regulatory landscape.

This guide has been prepared by Omnilingua, specialists in medical and technical translation. For more information on how we can support your IVDR compliance journey with expert translation services, please contact us at mkg@omnilingua.co.uk or visit www.omnilingua.co.uk.

**IVDR TRANSLATION
ISN'T JUST A BOX
TO TICK – IT'S A
CRITICAL
COMPONENT OF
SUCCESSFUL
MARKET ACCESS.**

