

Audit-Ready Italian IFUs under MDR and IVDR

A Practical Guide to Small and Mid-Size Medical Device and IVD Manufacturers



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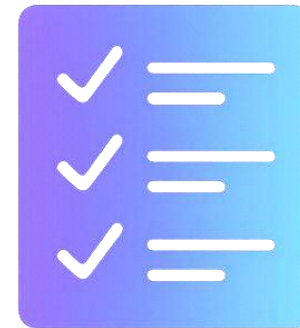
Why Translation Quality Matters in Your QMS

Under MDR and IVDR, IFUs are not just “nice-to-have” translations. They are controlled documents inside your Quality Management System (QMS). If your Italian IFUs are wrong, incomplete or inconsistent, these problems show up in your risk files, your audits, and your complaints log.



Common failure points

- ❌ Inconsistent terminology
- ❌ Warnings softened or mistranslated
- ❌ Layout changes that hide or break safety information
- ❌ Last-minute translations that delay submission or Notified Body (NB) review



QMS impact

- ❌ Non-conformities during ISO 13485 or MDR audits
- ❌ CAPAs triggered by documentation issues
- ❌ Extra cycles with NBs and competent authorities
- ❌ Higher risk of incidents linked to misuse

What MDR/IVDR Requires from Italian IFUs

MDR Annex I, Section 23 and IVDR Annex I apply directly to IFU content. For Italy, this translates into concrete requirements for language, safety and document control.

For a compliant Italian IFU, you need to verify that:

- ✓ Language is clear and adapted to the intended user (professional or layperson)
- ✓ Medical and technical terminology is correct and consistent with the technical file
- ✓ Safety wording for warnings, precautions and contraindications follows agreed patterns in Italian
- ✓ Symbols, abbreviations and units are used consistently across labels, IFUs and packaging
- ✓ Each IFU version is identifiable, traceable and under document control in your QMS
- ✓ Changes to the IFU are linked to risk management, PMS and NB feedback

IFU translation follows a written procedure, with responsibilities defined for RA, QA and the translation provider.

A Traceable Workflow Integrated with Your QMS

A good translation process is visible in your QMS. You can show who did what, when and with which checks.

Step	RA Role	QA Role	Provider	Timeline
Planning	Define scope, target users and languages. Share risk file and NB comments.	Confirm procedure and documentation requirements, including evidence to file.	Review QMS requirements. Share proposed workflow, glossary and style-guide plan.	Week 1
Translation	Provide controlled source files and any existing Italian wording.	Not involved, unless specific QMS checks are needed at draft stage.	Translate, build or update glossary and style guide, run first QA.	Week 3
Review	Perform SME review focused on clinical content and risk statements.	Verify that process steps were followed and issues are logged.	Revise, resolve comments, update terminology assets and change log.	Week 5
Approval	Sign off the final Italian IFU and related materials.	Update audit trail and confirm that controlled copies are released.	Deliver clean files plus bilingual review report and terminology list.	Week 6
Archiving	Integrate final IFU and translation dossier into the technical documentation.	Update risk assessment and internal audit plan if issues were found.	Provide certificate of translation, store project memory for future updates.	Ongoing

How I Help You Keep Italian IFUs Audit-Ready

You do not need another generic translation vendor. You need a process that fits your QMS and leaves a clear trail for auditors and Notified Bodies.

With each project, I can provide:

- Italian IFU translation aligned with MDR/IVDR and your device risk profile
- Bilingual revision focused on safety-critical content and usability for Italian users
- A compact translation dossier. process summary, roles, tools and checks performed
- Approved glossary, style guide and TM snippet, ready to file as controlled documents
- Change log showing how comments and risk-related updates were handled

Example:

I recently supported a European manufacturer updating their Italian IFUs for a Class IIb device. Through precise terminology harmonization and close alignment with their RA team, we prevented multiple terminological inconsistencies that could have delayed CE marking renewal



If you are preparing MDR or IVDR submissions, or updating IFUs for the Italian market, I can help you turn translation into a controlled, traceable part of your QMS instead of a last-minute risk.

Maria Luisa Barbano is an English-to-Italian medical translator and linguistic validation consultant with over 25 years of experience. She specializes in MDR/IVDR-compliant device documentation, clinical research materials and patient-facing texts, supporting RA and QA teams who need Italian content that is both clear for users and defensible in audits.



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