

MEDTECH • LIFE SCIENCE LOCALISATION

BEST PRACTICES FOR MEDICAL DEVICE TRANSLATION

A GUIDE FOR MANUFACTURERS

NN Translations
Your source of life science linguistic expertise



WHO WE ARE

- NN Translations specialises in life science and MedTech localisation.
- We support compliance with EU MDR/IVDR and global regulatory frameworks, including US FDA requirements
- We deliver accurate, compliant content for every target market.
- ISO 9001, ISO 17100 certified and ISO 13485-aligned workflows

Introduction

- MDR 2017/745 & IVDR 2017/746 and global regulatory frameworks (including US FDA requirements) require accurate, compliant documentation.
- Accurate, regulation-ready translations support global market access, patient safety, and compliance across jurisdictions
- Poor quality risks delays, withdrawals, and reputational harm.

MDR AND IVDR REQUIREMENTS

Language Compliance Under MDR & IVDR

- All user-facing docs must be translated/localised into the **EU official languages**
- Language must be **clear, legible, appropriate** to user profile
- **Non-compliance** = penalties or certification delays

FDA REQUIREMENTS

- All submissions must be in **English** (US FDA requirement)
- Foreign-language documents must include certified translations
- Translations must ensure accuracy, consistency, and version control
- Labelling and IFUs must be clear, legible, and compliant (21 CFR Part 801)
- Greater scrutiny applies to patient safety and risk-related content

COUNTRY-SPECIFIC LANGUAGE REQUIREMENTS

Each Member State has its own language policies.

- **Germany** requires all patient and professional content to be in **German**.
- **France** mandates **French** for all documentation.
- Some **Benelux countries** accept English for professional use but not for patient-facing material.

Manufacturers must verify requirements with national competent authorities before planning translation scopes.

DOCUMENT TYPES



Regulatory

IFUs, SSCPs, PMS reports, Declarations of Conformity



Marketing

Labels, packaging, implant cards, patient leaflets



Clinical

Clinical evaluation summaries, safety information

LANGUAGE STRATEGY & READABILITY

Target Languages

- Define target countries/languages early
- Prioritise languages that require earlier delivery
- Plan localisation budgets and timelines to avoid rush jobs

Layperson-Appropriate Language

- Use plain language, short sentences, active voice
- Replace technical terms with simpler equivalents if possible
- Add diagrams or visuals when needed

INFORMATION WE NEED BEFORE WE START

- **Project scope**: Type of document (e.g., IFU, SSCP, DoC, labels) and device class.
- **Intended users**: Professional, layperson, or mixed audience.
- **Regulatory framework**: MDR 2017/745, IVDR 2017/746, US FDA (21 CFR), and/or other applicable regulatory frameworks.
- **Target languages/markets**: Including any regional variants.
- **Delivery requirements**: File format, layout, design specifications.
- **Style & terminology**: Glossary, style guide, brand tone preferences.
- **Reference materials**: Past translations, diagrams, product images.
- **Review process**: In-country reviewers, subject-matter experts, approval steps.
- **Special considerations**: Symbols, abbreviations, QR codes, space restrictions.

ENSURING CLARITY & EXPERTISE

Readability / Usability Testing

- Test patient-facing content (IFUs, safety warnings)
- Use internal reviews, testing or cognitive debriefing

Native-Speaking, Subject-Matter Experts

- Native speakers with medical/regulatory translation & localisation experience only
- Must understand terms, device classification, MDR/IVDR structure

QUALITY & CONSISTENCY TOOLS

- **Glossary Development** – Maintain consistent terminology for device parts, safety terms, regulatory references; share glossary with all linguists and reviewers.
- **Term Validation** – Align terminology with Regulatory Affairs and Notified Body expectations.
- **Translation Memory (TM)** – Reuse approved translations/localisations, improve consistency, reduce cost/time.
- **Version Control** – Track all language versions and update consistently.
- **Audit Trail** – Keep translation/localisation history, linguist qualifications, and change logs.

REVIEW & COLLABORATION PROCESS

- **Four-Eyes Review** – Second linguist reviews every translation/localisation per ISO 17100.
- **Optional Back-Translation** – Use for critical patient-facing content or regulator requests.
- **Linguistic Sign-Off (LSO)** – Final layout check, symbols, abbreviations, QR codes.
- **In-Country Reviewers** – Local experts align translations/localisations with clinical practice and regulations.
- **Cross-Department Collaboration** – Coordinate with Regulatory, Clinical, and Marketing teams.
- **Supplier Qualification** – Prove vendors meet MDR/IVDR standards.

PITFALLS TO AVOID

What Can Go Wrong

- Using generalist translators
- Sole reliance on machine translation
- Ignoring updates or country-specific rules
- Skipping a 2-step review process and in-country review

High-quality translations & localisation protect patients, ensure compliance, and safeguard reputation

THANK YOU

Ready to Ensure Your Translations Meet Global Medical Device Regulatory Requirements (EU MDR/IVDR & FDA)?

Let's discuss how we can support your next project.
We are also proud to be an Associate Member of BIVDA.

info@nntranslations.com
www.nntranslations.com