

MEDTECH • LIFE SCIENCE LOCALISATION

CHOOSING THE RIGHT TRANSLATION PROVIDER

A GUIDE FOR MEDICAL DEVICE MANUFACTURERS & REGULATORY CONSULTANTS

NN Translations
Your source of life science linguistic expertise



WHY IT MATTERS

In the world of medical devices, translations are not just words — they are part of the safety profile and regulatory pathway of every device.

- Patient safety: unclear or mistranslated IFUs can result in misuse and harm.
- Regulatory compliance: MDR/IVDR require official-language documentation for each market.
- Market success: clear, trusted communication supports adoption by clinicians and patients.

Choosing the wrong provider risks delays, non-compliance, and recalls. The right provider reduces risk and builds confidence.

QUESTIONS TO ASK ANY TRANSLATION PROVIDER

Regulatory Expertise

- Do they know MDR/IVDR language requirements?
- Do they apply national guidance and local legislation?

Quality frameworks

- Are they ISO 17100 (translation), ISO 9001 (quality) and ISO 13485 certified?
- Do they provide a **Quality Manual, Regulatory Manual,** and **Quality Procedure on Handling Poor Translation Quality and Missed Deadlines** on request?

QUESTIONS TO ASK ANY TRANSLATION PROVIDER

Workflows

- Do they offer **translation + revision (ISO standard)** or just proofreading?
- Do they explain optional QA measures and workflows (in-country review, clinician review, linguistic sign-off)?

Terminology management

- Do they develop **glossaries, translation memories** and **style guides** with you?
- Do they follow MDR/, IVDR Article 2 and Annex I (Ch. III), EMDN, GMDN, IMDRF, labeling standards, national glossaries, etc.?

QUESTIONS TO ASK ANY TRANSLATION PROVIDER

Linguist qualifications

- How do they guarantee linguists are experienced in your device subfield?
- Can they provide **blind CVs** showing experience & qualifications?

Systems & security

- What CAT tools and TMS do they use for consistency and QA?
- Do they have clear **data security procedures**?

QUESTIONS TO ASK ANY TRANSLATION PROVIDER

Financial transparency

- Are Terms & Conditions visible and published on their website?
- Do they provide a clear **financial policy (invoicing, late payments, and cancellations)**?
- How is an **order/quote formally confirmed**?

🚩 **Red flag: vague answers, no published policies, or verbal-only commitments.**

GOOD ANSWERS VS RED FLAGS

Good Answers

Quality Process

✅ We follow ISO 17100: translation + revision by a second linguist.

Linguist Expertise

✅ Our linguists are preselected for device subfields (e.g., dental, diagnostic, cardio, etc.).

Glossaries

✅ We build client-specific glossaries and style guides upfront.

Red Flags

Quality Process

🚩 We do translation + proofreading only.

Linguist Expertise

🚩 We work with native speakers (without proof of device expertise).

Glossaries

🚩 We translate as we go, no glossary development process.

GOOD ANSWERS VS RED FLAGS

Good Answers

QA Measures

✅ We recommend clinician review for high-risk documents like IFUs or SSCPs.

Transparency

✅ Here are our Terms & Conditions, Manuals, Financial Terms

Workflows

✅ We recommend the right workflow based on document type and risk — no steps skipped.

Red Flags

QA Measures

🚩 We only add extra steps if the client insists.

Transparency

🚩 We'll send some generic documents or we'll clarify the details once the project starts.

Workflows

🚩 You pick the workflow or mix steps yourself.

TAKEAWAY & CHECKLIST

✅ **Your translation provider should:**

- Understand MDR/IVDR language requirements and local standards.
- Provide ISO certifications and quality documentation.
- Offer fit-for-purpose workflows, not one-size-fits-all.
- Guarantee qualified linguists in your device subfield.
- Deliver glossaries, style guides, and translation memories
- Recommend best practices, not just follow instructions.
- Be fully transparent about terms, finances, order confirmations and data security.
- And more...

Choosing **the right partner** is about more than price. It’s about **reducing compliance risks, protecting patients**, and **enabling smooth market access**.

ABOUT NN TRANSLATIONS

We are a boutique provider of life sciences translations and regulatory language consulting.

- Specialized in **MDR/IVDR-compliant medical device translations**
- EMA-aligned submissions & linguistic validation of COAs
- ISO 17100 & ISO 9001 certified aligned with ISO 13485
- Transparent terms & clear financial policies

- PDF Accessibility
- User Interface (UI), Graphic User interface (GUI) Electronic Implementation
- in-App / in-Context review after Electronic Implementation
- Readability / Usability testing (IFUs, PILs, patient-facing content)
- Translation Evidence Packages
- Webinars & Consultancy on translation best practices for medical device entities, etc.

THANK YOU

Ready to Ensure Your Translations Meet EU MDR/IVDR and National Standards?

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

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