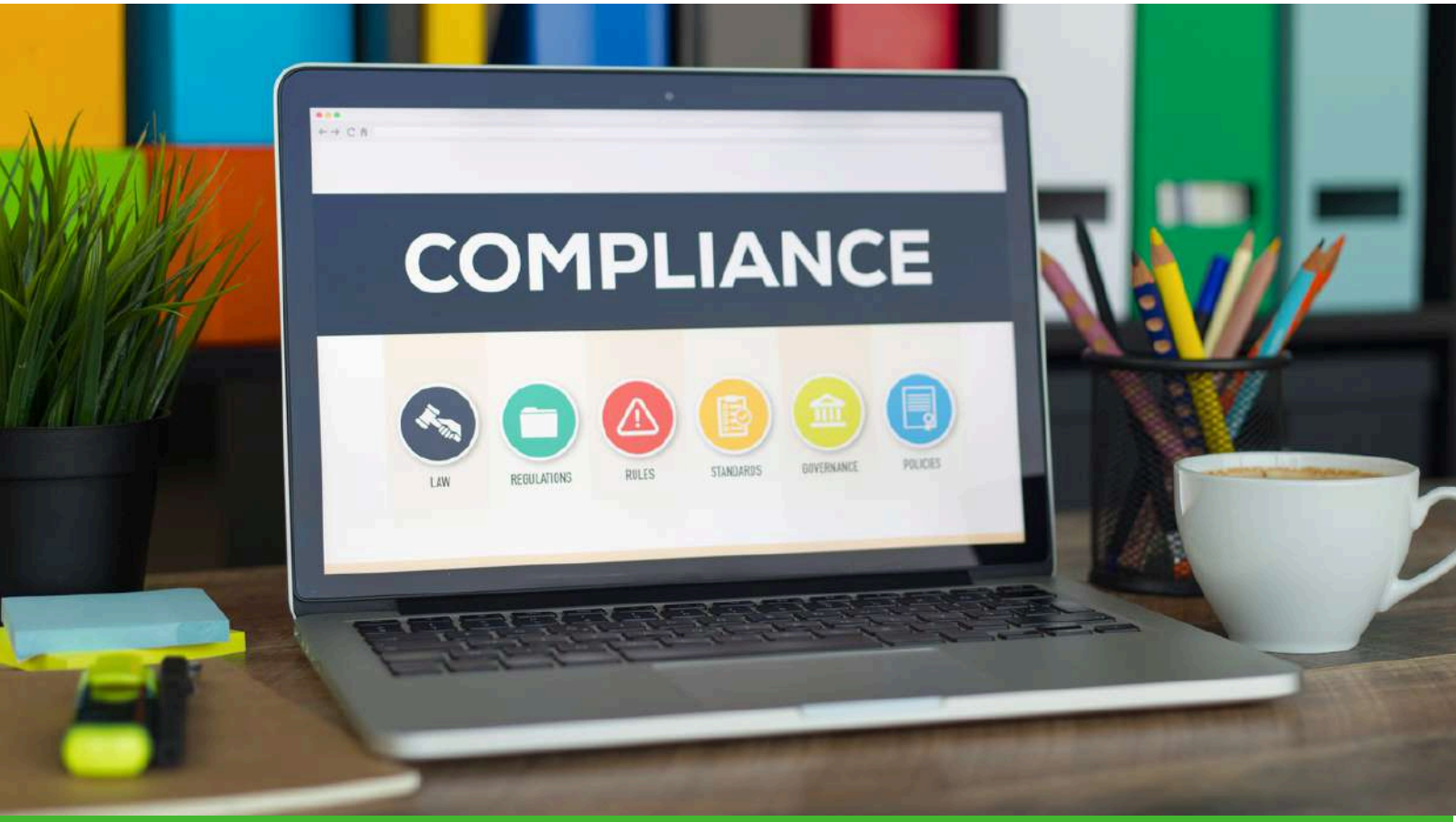
DUAL UK/EU COMPLIANCE TRANSLATION CHECKLIST 2026



A Practical Reference for Medical Device Manufacturers Operating Across Both Markets

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WHO WE ARE

For over 25 years, Omnilingua has been the trusted translation partner for medical device manufacturers operating across UK and European markets.

Our speciality? Supporting companies through exactly the kind of regulatory complexity that dual UK/EU compliance creates — from technical documentation and terminology management through to patient-facing localisation across multiple markets.

Our network of translators are not just linguists, but subject matter experts who work exclusively in their native language and specialist regulatory fields. When the difference between GMDN and EMDN terminology matters, you need people who understand why.

We've embraced innovation without sacrificing quality, combining Translation Memory Software with Neural Machine Translation to deliver consistency and efficiency across large, complex documentation programmes.

This checklist will guide you through the key stages of managing dual UK/EU compliance translation — so nothing gets missed, and nothing gets assumed.

TRANSLATING COMPLEXITY WITH EXPERT PRECISION FOR OVER 25 YEARS

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STAGE 1: BEFORE YOU START: KNOW WHAT YOU'RE DEALING WITH

The UK and EU regulatory frameworks are moving closer together — but they are not the same. Before any translation work begins, establish exactly what each market requires from you.

- Confirmed which devices are in scope for EU MDR, UK MDR, or both
- Confirmed device classification under each framework separately — up-classification rules differ
- Identified which documents are required for each market — do not assume the lists are identical
- Confirmed which nomenclature system applies: GMDN for UK, EMDN for EU
- Noted where the two frameworks diverge for your specific device category

STAGE 2: SET UP YOUR TRANSLATION PROGRAMME

Before translation begins, your programme needs the right infrastructure. These are the foundations everything else depends on.

- UK and EU translation workstreams set up independently — not a single workflow applied to both
- Separate terminology glossaries created for UK (GMDN) and EU (EMDN) documentation
- Translation Memory databases separated by market — confirmed with your translation partner
- UK Responsible Person (UKRP) appointed and DORS account updated (deadline: 30 March 2026)
- EUDAMED Actor Registration underway — required before UDI/device data can be submitted
- Translation milestones built into your product launch schedule from the outset
- Translation partner confirmed as having working knowledge of both UK MDR and EU MDR frameworks

THE DECISIONS YOU MAKE BEFORE TRANSLATION BEGINS DETERMINE THE QUALITY OF EVERYTHING THAT FOLLOWS.

STAGE 3:
TECHNICAL DOCUMENTATION

- Source documents finalised and proofed before translation begins — late changes cost time and money
- GMDN terminology applied consistently throughout all UK documentation
- EMDN terminology applied consistently throughout all EU documentation
- UDI data, device identifiers and labelling references locked down before translation — must be consistent across all language versions
- Version control system in place that tracks UK and EU documentation separately
- In-country regulatory reviewer engaged for EU documentation — separately from UK review
- In-country regulatory reviewer engaged for UK documentation

STAGE 4: PATIENT-FACING DOCUMENTATION

Patient-facing materials require localisation, not just translation.
Treat this as a separate workstream.

- Implant cards and lay-user IFUs identified and separated from technical documentation workstream
- Market-specific versions planned for each EU member state where device will be marketed
- UK patient-facing documentation scoped against MHRA standards independently of EU versions
- Localisation brief prepared for each market — tone, readability level, cultural considerations
- Readability review by native-speaking in-country reviewer confirmed for each market version
- Patient-facing workstream built into overall timeline early — not treated as an end-of-project add-on

A PATIENT READING AN IMPLANT CARD AFTER SURGERY NEEDS CLARITY, NOT REGULATORY PRECISION. THESE ARE NOT THE SAME THING

STAGE 5: PRE-SUBMISSION CHECKS

- EUDAMED registration data cross-checked against all translated documentation for consistency
- DORS submission prepared independently — not assumed to be covered by EUDAMED submission
- All language versions checked for consistency with UDI data and device identifiers
- In-country regulatory review completed for both UK and EU documentation
- Final version control check — confirm UK and EU versions are correctly separated and labelled
- Submission timeline confirmed for each market independently

STAGE 6: ONGOING MONITORING

- MHRA roadmap and UK pre-market SI consultation outcomes being actively tracked (consultation open until April 2026*)
- Translation schedules include contingency for UK pre-market SI changes — timelines not yet confirmed
- Process in place to update translations if either framework changes post-submission
- Lessons learned documented — terminology decisions, workflow issues, timeline pressures
- Translation memories and glossaries updated following completion of project

THE UK PRE-MARKET SI IS STILL BEING FINALISED. A TRANSLATION PROGRAMME WITH NO FLEXIBILITY BUILT IN IS A PROGRAMME WAITING TO FAIL.