

*If You Don't Understand It, You Can't Translate It!*

## At a glance

Medical device technical files include essential regulatory, clinical, manufacturing, and design documentation required for global market approval. Accurate translation ensures regulatory compliance, streamlines market entry, and supports device safety, performance, and quality standards worldwide.

### Key metrics



**35%**

Faster global regulatory approval timelines



**99.7%**

On Time Delivery



**100%**

Regulatory Compliance

## CHALLENGES



Technical files involve complex technical terminology, precise regulatory language, and detailed documentation that must be translated without error. Inaccuracies can result in regulatory rejection, compliance issues, market entry delays, or costly audits. Ensuring consistency, accuracy, and alignment with global standards across multiple languages, under strict regulatory timelines, adds significant complexity to the translation process.

## SOLUTIONS



AI-optimized translations combined with expert medical device regulatory linguists ensure technical files comply precisely with international regulatory requirements.



**Technical File Specialists**



**12 Step Quality Control Process**



**Scalable To Meet Your Needs**

## BENEFITS



**1**

### Accelerated Global Approvals

Accurate translations expedite regulatory reviews and global market entry, shortening time-to-market.

**2**

### Improved Regulatory Confidence

Precise, compliant translations reduce regulatory queries, audits, and risks, protecting market strategies.

**3**

### Reduced Compliance Risk

Consistent translations ensure adherence to quality standards and device specifications, safeguarding patient safety globally.