

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

At a glance

Clinical Evaluation Reports (CERs) provide essential evidence of medical device safety, performance, and clinical benefits for regulatory approval worldwide. Accurate translations ensure regulatory compliance, maintain scientific rigor, and streamline global market access.

Key metrics



35%

Reduction in regulatory
approval timelines



99.7%

On Time Delivery



100%

Regulatory Compliance

CHALLENGES



Clinical Evaluation Reports include complex clinical, regulatory, and scientific data requiring meticulous translations. Any inaccuracies or inconsistencies can compromise data integrity, delay regulatory approvals, or trigger audits. Maintaining scientific accuracy, regulatory compliance, and clarity across multiple languages and stringent deadlines adds significant complexity to the translation process.

SOLUTIONS



AI-optimized translations combined with specialized medical device linguists ensure precise, compliant translations of CER documentation globally.



**CER Translation
Specialists**



**12 Step Quality
Control Process**



**Scalable To Meet
Your Needs**

BENEFITS



1

Accelerated Regulatory Approvals

Precise CER translations streamline regulatory reviews, speeding up global device market entry.

2

Enhanced Data Integrity

Accurate translations maintain scientific credibility, ensuring reliable clinical evaluation outcomes and regulatory acceptance.

3

Reduced Compliance Risk

Compliant translations mitigate regulatory queries, audits, and delays, safeguarding market strategy and product reputation.