

Introducing the Only Notified Body-Endorsed Risk Management Method for Website Translation



The Opportunity

As device and IVD companies look for more effective means of communicating with practitioners and patients, electronic delivery of product information over the web is gaining importance. Via the Internet, companies have immediate access to every worldwide market that they serve.

The Challenge

Notified Bodies consider websites that contain product information to be “labeling”—subject to current labeling and risk management requirements of ISO 13485:2003, IEC 60601, and ISO 14971:2000. Multilingual (translated) websites are subject to the same regulatory and risk management requirements as the English language originals - version control for updates can be especially challenging. In fact, because of conformity requirements of the MDD and IVDD, Notified Bodies have declared translation an “important outsourced service” subject to the stringent outsourced vendor requirements of ISO 13485:2003 and ISO 14971:2000.

The Crimson Solution

Crimson’s process for website translation is built on the world’s only ISO 13485:2003 certified and ISO 14971:2000 endorsed translation quality system. The process includes BackEditing™—the only translation risk management process to receive official Notified Body endorsement.

By combining BackEdit™ with Crimson’s adaptation of the SAE J2450 translation quality metric (reviewed and approved by KEMA Notified Body), clients can eliminate the costly and time-consuming step of “distributor review” (case study and regulatory approvals available at www.medical.crimsonlanguage.com).

In fact, Crimson’s process for translation risk management is so effective, it’s patent-pending. Through our parent company, Translations.com, Crimson offers cost-effective Globalization Management Software that provides an automated, auditable solution for multilingual updates and version control. Clients who work with Crimson receive:

- A compliant, documented procedure for website translation (localization) that’s suitable for inclusion in your Risk Management/Technical file
- A translation/localization process that satisfies current ISO 13485:2003, IEC 60601, and ISO 14971:2000 risk management requirements
- Best-of-Class technology solution (GlobalLink) provides effective version control and auditable reporting for website updates
- The world’s only ISO 13485:2003 controlled website localization process
- The world’s only Notified Body-approved translation risk management process
- The world’s only Notified Body-approved process to eliminate distributor review

Call Crimson now and take the guesswork out of your website and labeling translation. Our credentials, processes, and experience can help reduce your overall “cost of compliance” for multilingual labeling.

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The Easiest Way for
You to Satisfy

ISO 13485:2003,
MDD, and IVDD
Requirements
for Website
Translation

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