

## CE Marking, Translations, and the IVD Directive (IVDD 98/79/EC)

By John Balchunas

Country specific regulation of all products is nothing new for the *in vitro* diagnostic (IVD) medical device industry, which encompasses a wide range of instrumentation and reagents designed for the detection and diagnosis of infection. Complying with FDA requirements, the industry is accustomed to the proper labeling, documentation, and quality assurance of all products. However, a relatively new directive issued by the European Union (EU) has expanded the regulatory requirements of all IVD medical devices. The *in vitro* Diagnostic Directive (IVDD), which becomes law on December 7, 2003, requires all medical devices bear the CE mark. IVD medical devices bearing the CE mark have satisfied defined language, safety, quality, and performance requirements for EU member countries.

Since the formation of the EU after the Second World War, member countries continue to bolster a single market economy. The EU has focused largely on health and safety concerns of products marketed in the European Economic Area (EEA) by issuing a number of industry specific directives. Consequently, many technical communicators and translation agencies in these regulated industries are becoming familiar with all the complexities involved in writing for the international community.

For technical communicators in the IVD industry, much attention focuses on the translation of all operator manuals,

package inserts, and labeling in order to satisfy CE marking language requirements (see inset box). Translation into upwards of ten languages for products heavily marketed in the EEA is not uncommon. This translation of user documentation raises a whole new set of challenges for technical communicators in the IVD industry. These challenges include:

**Cost.** The cost is enormous for the translation of package inserts, labeling, and operator manuals. Documentation departments are relying heavily on the use of translation memory services, streamlined document layout, and internationally approved symbols to help mitigate translation costs.

**Label Space.** All product labeling must meet the language requirements of the target countries. As a result, labeling specialists are faced with the challenge of fitting translations on

### CE Marking Language Requirements for the EEA

**Austria, France, Greece, Ireland, Italy, Portugal, Spain, and the UK** all require use of the respective national language.

**Belgium.** Dutch, French, or German for professional use. All three for patient use.

**Denmark.** Danish. Other languages are negotiable.

**Finland.** Finnish, Swedish or English, unless the information takes the form of generally known directions or warning symbols. Information intended for users or patients to ensure the safe use of the device must be in Finnish and Swedish.

**Germany.** German. Other EU languages may be used for non-safety data.

**Iceland.** Icelandic (or other languages understandable to the professional user such as Finnish or Swedish)

**Luxembourg.** English for professional use. Any patient information in French, German and Liezeburgish.

**Netherlands.** Dutch. English negotiable for professional use.

**Norway.** Norwegian. English accepted for professional use.

**Sweden.** Swedish. English negotiable for professional use.

**Switzerland.** French, German, and Italian. Romanish also acceptable.

a wide range of instrument, carton, and reagent labels. Due to limited space on most labels, much of the push has moved toward the use of internationally approved symbols.

**Time.** Translations take time. As documentation departments grow accustomed to obtaining translations for all documentation, project teams must be made aware of the impact translations play on project timelines.

As the *in vitro* diagnostic medical device industry races to meet the December 7, 2003 deadline required by the IVDD, the industry continues to evolve, becoming increasingly aware of the needs of the international community.

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