



Missing or Making the Mark: CE Mark deadline looms over U.S. companies

Are U.S. firms ready for new European requirements?

U.S. companies that sell medical devices in Europe may be in for a rude awakening on June 14, the day that a broad new set of medical device regulations, represented by the CE Mark label, goes into effect in Europe. The implementation of the CE Mark rules was designed to harmonize regulations between different European nations, but it could strike a discordant note with U.S. companies not prepared for the new regulatory environment.

With the June 14 deadline less than one month away, a surprising number of U.S. firms remain in the dark about what they need to do to attain CE Mark certification, and the ramifications of failing to do so. Indeed, some market watchers estimate that as many as 40% of medical devices currently on the European market don't comply with the CE Mark rules. The companies that manufacture these products risk losing access to the largest overseas market for medical devices.

“Small manufacturers are having problems, and some are in big trouble.”

Harmonizing European regulations

The CE Mark is part of the Medical Devices Directive (MDD 93/42/EEC), which was passed by the European Union three years ago as part of the EU's desire to harmonize regulations across participating countries. The CE Mark was designed to make life easier for device manufacturers by creating an approval process that, once completed, allows device companies to sell CE Marked-products in all EU countries.

Prior to the CE Mark, device firms had to receive regulatory approval from each country's authorities, a time-consuming process. The MDD stipulates that all medical devices, except in vitro diagnostics, active implantables, and medicinal, cosmetic, and personal protective devices (which are regulated by separate directives), must bear the CE Mark as of June 14, 1998 to be sold within the European Union.

To obtain the CE Mark, a manufacturer must work with a Notified Body, a European organization that has been approved by an EU Competent Authority to audit firms for compliance with the directive. A weekly publication entitled the Official Journal of the European Commission (“OJ”) publishes a list of approved Notified Bodies.

Notified Body inspections and audits include review of a manufacturer's quality assurance system, safety practices, testing procedures, and, for new technologies, adherence to existing practices. Upon conclusion of a successful audit, the manufacturer, by virtue of the EC Declaration of Conformity, confirms that their product meets the directive's requirements and thus qualifies for the CE Mark.

This process can last several months, according to Reiner Krumme, head of the medical division at TÜV Rheinland USA, a Notified Body that audits companies for CE Mark compliance.

“There is no typical cycle. It depends on the management team's commitment and understanding of the issues,” Krumme said. “Time frames can range from two to 12 months. If it takes longer than 12 months, usually this means that something is wrong.”

U.S. firms without the Mark are at a disadvantage

Although the June 14 deadline for implementation of the CE Mark has been public for three years, some manufacturers have paid it scant attention and find themselves scrambling to comply, while others already are in compliance.

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“Larger companies and manufacturers of active devices have a definite advantage,” commented Marie O'Connell of the National Standards Authority of Ireland (NSAI). “Small

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Cultural differences also lead to erroneous assumptions, O’Connell noted.

“Seventy percent of our clients are from the U.S.,” she said. “In the States, there is a culture of FDA approval, which is a good basis. But it’s not enough. The European standards we use to evaluate quality systems differ from American standards, and this new approach can prove difficult for a U.S. company. Companies with an ISO culture, however, have a much better understanding of our standards and thus tend to do well.”

Companies which fail to comply with the CE Mark rules risk fines, penalties, and the possible removal of their products from the market. However, products currently on the market that are not in compliance as of June 14 will not be removed right away. A grace period of three years recently was negotiated for such cases. Apart from potential fines and penalties, trying to sell a device without the CE Mark is a risky gambit.

“CE Marking has a value in the marketplace,” stated O’Connell, who also serves as chairperson of the European Commission’s Notified Bodies Working Group for Medical Devices. “End users and purchasers understand what it means — safety, proper technical specifications, and added assurance.”

And with U.S. firms selling \$3.6 billion worth of devices to the EU, a number expected to climb to \$4 billion in 1998, missing the Mark is a risk worth avoiding.

Language requirements are country-specific

Acquiring the CE Mark is only the first step to successful penetration of EU markets. Though the directive is an attempt to unify EU country medical devices standards, member states are allowed to add their own requirements and regulations. This could increase the regulatory burden on medical device manufacturers.

Additional regulations vary greatly from country to country. The U.K. and Ireland more or less have adopted the language of the directive into their respective laws. France, on the other hand, has added a plethora of additional requirements in areas such as labeling, pre-market regulations, and translation of product documentation into French.

In fact, translation into country languages is not addressed by the directive, and has been left up to the member states to regulate. France has very specific requirements, and it is impossible to sell a device there without translating all product documentation, e.g., instructions for use (IFU), labeling, and packaging. Other countries, such as Germany and Sweden, have no stated requirements. This does not

mean, however, that device manufacturers can ignore translation issues.

“It’s a matter of practicality,” observes TÜV Rheinland’s Krumme. “For example, the typical German device end-user is a nurse. A German nurse likely speaks conversational English but is not trained in medical English. Translation is a safety issue.”

While such facts underscore the importance of providing accurate translations, overall language requirements represent a murky area. Currently, the EU is considering a proposal to require that device documentation must be translated into 13 languages. However, this seems unlikely to become part of the directive’s language, according to O’Connell.

“One has to take a sensible approach,” she said. “Is this proposal pragmatic? What benefit is it to have IFUs in 13 languages, especially if the firm is selling its product only in France and Germany?”

“CE Marking has a value in the marketplace”

Nevertheless, translation is a necessity in major European markets. In some countries this is due to legislation, while free-market competition forces the issue elsewhere. Acquiring the CE Mark and providing technically accurate translations are definite prerequisites in the major European markets, which include France, Germany, Italy, and Spain.

Firms seeking CE Mark compliance should contact a certified Notified Body. The aforementioned “Official Journal” of the European Commission is a good starting point and can be accessed via the World Wide Web at <http://eur-op.eu.int/indexen.htm>. Furthermore, NSAI and TÜV Rheinland are approved Notified Bodies and publish information about their services on the web. The URL for NSAI is <http://www.nsaicert.com>, and TÜV Rheinland can be found at <http://www.us.tuv.com>.

Future editions of this newsletter will track and report on other regulatory developments, especially as they pertain to languages and translation issues.

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