



OCTOBER 2009

Addendum to:

“Hello, Europe. Be the first to meet my new product.”

Our last Pulse article about when and how to introduce your pharmaceutical or medical device in Europe generated a lot of interest. Clearly, many of you have been thinking — or this article got you started thinking — about a European product launch.

In the article, we touched on the European Union's (EU) requirement that medical devices be issued a CE Mark before they can be marketed. Because we received requests for more information on this, we decided to do an addendum to the article to answer a few of your questions.

The CE Mark certifies that the product meets EU standards for health, safety, quality and the environment. Once a medical device has received CE Marking, it can be marketed in all the EU countries (currently 27) without undergoing additional scrutiny or requirements from individual countries.

The first step is to determine your product's risk class: Class I are considered low risk (e.g. wheelchairs), Class IIa are low-medium risk (hearing aids), Class IIb are medium risk (ventilators) and Class III are high risk (prosthetic heart valves, for example).

You can determine your product's risk class by consulting the Medical Devices Directive (MDD), the Active Implantable Medical Devices Directive (AIMDD) or the In Vitro Diagnostic Medical Devices Directive (IVDD).

The requirements and standards for each class are outlined in the directives. ISO certification is not mandatory to meet CE Marking requirements, but compliance with ISO 13485, which outlines a comprehensive management system for the design and manufacture of medical devices, is certainly a plus.

Low risk devices can be "self certified," meaning that once you have determined that your device is low risk and you have met the requirements of the relevant directive, you can place the CE Mark on your device. Higher risk devices require that a "Notified Body" audit your quality system to certify that you have complied with all requirements as laid out in the applicable directive. A Notified Body is an organization recognized by the European Commission to approve medical devices covered in the directives.

A well-designed European Opportunity Assessment will help you understand how your device should be classified, whether a Notified Body audit is required, and how to certify your medical device and implement and manage your quality system in a way that maximizes your market opportunity.

Special thanks to Glenn Neuman of New World Regulatory Solutions (www.newworldreg.com) for his valuable input in this expanded explanation of EU regulatory requirements.

If you missed the original article, or want to know more about European Opportunity Assessments, read "Hello, Europe. Be the first to meet my new product." You can find it [here](#) on our website.

To our Subscribers: *If you want to generate more sales by launching your product on the other side of the Atlantic, please contact Robert Keefer or Reinhard Merz for a free consultation and to see if we might be of assistance. In today's fast-pitched world and pinched economy, every new market can bring tangible value to you. We can help you think through your options, and we would enjoy working with you. Our phone number in NC is 919-354-4204, and in Germany it is +49 6221-27262.*



To contact the publisher and editor of Pulse©, or to learn more about how TCG can help you, please contact rkeefe@tcgbiopharma.com.

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