

# THE 2010 MEDICAL DEVICE DIRECTIVE CHANGES: IS YOUR COMPANY READY?

**Nashua, New Hampshire, March 24, 2008** – If your company manufactures medical devices that are placed on the European Market, the clock is ticking to address the changes that will be coming into effect within the Medical Device Directive in 2010. In just over 18 months, companies that currently have a CE Marking, or are trying to achieve CE Marking for new products, may face unnecessary delays or even lose certification, if they're not now taking steps to ensure they comply with the new requirements..

“In September of 2007, a new medical device directive, 2007/47/EC, was approved. The new directive sets out to clarify and update the current medical devices directive (MDD) and active implantable medical devices directive (AIMD),” says Claire McKenna, Medical Device Program Manager with the National Standards Authority of Ireland, Inc. “While most of the changes are truly clarifications, there are a number of changes that can drastically effect how companies achieve CE Marking for their products. Companies need to be planning for these changes now as not to delay their European market access in 2010.”

McKenna outlines what she sees as the changes that will have the most impact on the medical device industry:

**Clinical Data** – “The biggest change in the directive is in the area of clinical evaluations. Currently, there is a requirement for companies to provide clinical data for their medical products, but the requirement was never very clear and therefore not effectively applied by many companies,” McKenna explains. “The new regulations, however, specifically define what clinical data is and what

companies are expected to do to ensure safety and demonstrate the performance of their devices.”

One way to do this is to prove that the product has been clinically tested or that published data can be used in lieu of clinical testing. But that will change in 2010.

“In the past, companies often cited other similar products’ clinical data to support their CE Marking application, but this will be examined in greater detail under the new directive,” says McKenna. “If your company makes a high risk device, you are currently able to reference the testing data for similar devices. In 2010, the ‘literature comparison route’ will require exact device comparisons. Given these changes, we anticipate that companies will be performing more of their own clinical investigations to demonstrate compliance, particularly for novel or high risk products.”

**What is a Medical Device** – Another change is the definition of a medical device. Software that is intended for diagnostic or therapeutic purposes will, for the first time, be classified as a medical device. This means that many software designers will have to have their products CE Marked prior to release in Europe.

**Classification** – “The new directive also has changed the classification rules and some definitions. For example, the central circulatory system has been extended to the bifurcation of the aorta, and now surgically invasive devices for transient use will be regulated,” says McKenna. “These devices are currently lower risk devices but under the new directive will be considered Class III, high risk devices. Companies may be very surprised to find that a product they are currently marketing will be required to have a design dossier or require a different CE Marking route after 2010.”

**Post Market Surveillance** – In another major change to the directive requires companies to conduct sustained and coordinated clinical post market surveillance of their products.

“Companies have always been required to have a ‘vigilance system’ in place so that they could react to any issues that might arise once their product went to market, such as unintended deaths or unexpected complications” says McKenna. “But under the new directive the rules are further tightened. Companies will now need to have a system in place that proactively monitors how their devices are being used and are performing in the field. There will be significantly more emphasis placed on post-market clinical follow-up as part of the post-market surveillance plan. Companies will have to keep close tabs on their products and have a system in place to report, and react to, any unexpected changes once their products are released into the marketplace.”

McKenna says despite the fact that the changes have been published since September 2007, she doesn’t see many manufacturers taking the necessary steps to ensure they meet the 2010 deadline.

“Many of the changes are significant and are not able to be made overnight,” says McKenna. “Companies need to start looking at their products in such a way as to ensure that they have the correct data and systems in place come 2010.”

Her advice? Start speaking to a notified body now to find out how the changes will affect your company and to determine what, if any, extra steps you may be required to take to ensure that you are prepared. This is especially important for products that are already on the market since the certification needs to be re-issued after a maximum of 5 years.

“The last thing a company wants to do is have a successful product pulled from the market in 2010 because it didn’t have all the proper data ready when it came

time for recertification,” says McKenna. “There is definitely a prevailing attitude in the market that companies have plenty of time to get ready. But if you look at it, you’re talking only seven business quarters, which considering the changes, is not a lot of time. This is one of those cases where companies need to start taking proactive steps now to make sure they can stay ahead of the regulatory curve because 2010 will come up quickly.”

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