



Progress Report May 2009

LNE/G-MED: Sharing a Passion for Progress

LNE and G-MED North America (LNE/G-MED) would like to provide our valued Medical Device customers with periodic updates on the status of various regulatory and quality related issues. As a complimentary service to help you best determine your current and future certification needs, we provide you with the following updates:

Status of EN 60601 -1, 3rd Edition

EN 60601 is the *European* harmonized standard used to demonstrate the basic safety and essential performance of medical electrical equipment. Its requirements are strictly the same as in the international standard IEC 60601 hence the 3rd Edition of IEC 60601, published in 2005, is a *global* harmonized standard for electrical and mechanical safety conformance in the medical field. The adoption of this standard in the international market has been evolving rapidly and IEC / EN 60601 3rd Edition significantly changes the way electro medical devices are assessed. LNE can evaluate your medical device to the 3rd Edition and meet your testing needs.

Date of Withdrawal (DOW) of EN 60601 -1, 2nd Edition

The date of withdrawal (DOW) of EN 60601 -1, 2nd Edition is the date after which compliance to the standard ends and presumption of compliance to the European Directive becomes absolute. Although the text of the EN 60601 -1, 3rd Edition standard mentions September 12, 2009 as the date of withdrawal of the 2nd Edition, it was determined by the European Committee for Electro Technical Standardization (CENELEC) that the deadline can not be met without incorporating the collateral parts of the 3rd edition family standard (EN 60601 -1-xx) such as EN 60601 -1-2, EN60601-1-3, EN 60601-1-6, EN 60601-1-8, etc. Therefore CENELEC recently agreed on an extended transition period and the new DOW is now set for June 1st 2012. This deadline is the same for all collateral parts of the standard. Nevertheless, for the products subject to particular requirements described in EN 60601 -2-xx standard (part 2) referring to the 2nd edition of EN60601 -1, this standard still remains valid until the part 2 standard becomes obsolete itself (which may occur after June 2012). Note that the new deadline was also adopted by Health Canada who published a statement confirming their recognition of the IEC 60601 -1, 2nd edition standard to June 1st 2012.

The European Union and EN 60601 -1

Under the EU New Approach Directives, Notified Bodies are required to issue certificates to products that meet the Essential Requirements and perform an evaluation of equivalency data presented. This assessment is achieved by demonstrating presumption of conformity to the harmonized standard or by equivalent methods. The Notified Body may accept testing to the 3rd edition as a presumption of conformity once the IEC 60601, 3rd Edition becomes a harmonized standard. However until the 2nd edition is made absolute, the Notified Body will also accept conformity to the 2nd edition of the standard as a presumption of conformity with the relevant requirements of the Medical Device Directive (MDD).



Clinical Evaluation of Medical Devices: Meeting the European Essential Requirements for the CE Marking

With Directive 2007/47/EC revising the Medical Devices Directives (MDD and AIMD), clinical evaluation of medical devices is no longer an option. The requirements have been clarified and manufacturers must evaluate this impact on their activities. The deadline for full implementation is March 21, 2010. It is time to take action and assure the compliance to the essential requirements applicable to your medical device. LNE/G-MED offers a new intensive 1-day training on the Clinical Evaluation process (limited to 20 trainees). To register by telephone call (301) 495 0477 or E-Mail your registration request to GMEDNA@LNE-GMED.com.

Dates and Locations:

June 2, 2009 (8:00 am – 5:00 pm EST) – Washington, DC area
September 29, 2009 (8:00 am – 5:00 pm PST) – San Francisco, CA
October 27, 2009 (8:00 am – 5:00 pm EST) – Boston, MA
Cost: US \$890

Medical Design & Manufacturing (MD&M East) Exposition & Conference, June 8 -11 2009, Jacob Javits Convention Center, New York City: Visit LNE/G-MED and register to win a free bottle of fine Bordeaux wine (booth #2737)

MD&M East is the premier East Coast annual conference for medical manufacturing professionals involved in R&D, design, engineering manufacturing, quality and regulatory affairs. LNE/G-MED is once again exhibiting and would like to learn more about your products and services as well as introduce you to our team of engineers. To thank you for your time and effort, you will be registered to win a bottle of fine Bordeaux wine. In addition, if a Request for Proposal (quote) is desired, you may fill out our *Application for Certification of Medical Devices* form provided at our booth (#2737) and receive a complimentary bottle of wine. For appointments or if LNE/G-MED can be of assistance regarding any of your testing, training, regulatory or quality management needs, please feel free to contact us or visit booth #2737.

For more information

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