



## FOR IMMEDIATE RELEASE

### **Biolux Research Announces ISO 13485 Quality System Certification and CE Mark Regulatory Approval of the OsseoPulse™ Bone Regeneration System.**

**VANCOUVER, B.C., CANADA – Feb. 5, 2009** – Biolux Research Ltd. is pleased to announce today two news items that will further enhance the commercialization of its OsseoPulse™ Bone Regeneration System.

The company has successfully completed its ISO 13485 certification audit and has been awarded a final certificate. ISO 13485 is a worldwide-recognized medical device quality system standard, and certification to this standard is a requirement for any medical device company to develop, manufacture, and market products in Europe, Canada, and other markets. The Biolux quality system was audited by BSI Management Systems America Inc., one of the foremost auditing bodies in the world.

The company has also received a CE Mark certificate in accordance with Annex V of the Medical Device Directive 93/42/EEC, with BSI acting as the Notified Body and issuing the certificate. Achieving the CE Mark allows Biolux to market the OsseoPulse™ directly to the 27 countries within the European Union plus the additional 4 countries that recognize the CE Mark. This market is comprised of approximately 400M people. The dental implant market in Europe represents approximately 40% of the worldwide implant market, and is thus a significant market for Biolux and the OsseoPulse™.

“We are very pleased to have achieved both ISO 13485 and the CE Mark,” states Kevin Strange, President and CEO of Biolux. “We are committed to producing high quality products and services for our distributors and customers. Attaining CE Mark allows us to approach European distribution partners with regulatory approval already in hand, which facilitates more timely access to a very large and progressive dental implant market. In addition the combination of ISO certification and CE Mark opens the door to other non-EU markets.”

#### **About Biolux Research**

Biolux Research Ltd. is a world leader in the development of light activated bone regeneration systems for dentistry. Biolux focuses on product development, clinical and basic research, and its proprietary, patent-pending OsseoPulse™ Bone Regeneration System is premised on a vision to transform the practice of implantology and oral surgery in dentistry by accelerating implant integration and bone regeneration in a safe, effective and non-invasive approach.  
[www.bioluxresearch.com](http://www.bioluxresearch.com)

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