



**PRESS RELEASE**  
*For immediate Dissemination*

## **OPSENS RECEIVES KEY ISO 13485 CERTIFICATION FOR FFR PRODUCTS**

**Quebec City, Quebec, September 13, 2011 – OPSENS Inc. (“Opsens”) (TSXV: OPS)** has received ISO 13485 certification for its medical activities from BSI Group (a leading global business services organization providing standards-based solutions in more than 150 countries). This certification is key to the development and commercialization of its products designed for the measurement of Fractional Flow Reserve (« FFR »).

### **Opsens’ product for FFR to access market in 2012**

Fractional flow reserve or FFR is an index of the functional severity of coronary stenoses calculated from pressure measurements taken before and after narrowing of arteries discovered during coronary angiography. FFR measurement is an increasingly popular method used in the treatment of cardiac lesions. The FAME Study, published in 2009, outlined the positive outcome this cost effective step has on patients’ recovery and overall outcome.

Opsens’ has developed two products for the measurement of FFR. First, the **OptoWire**, a guide wire instrumented with a fiber optic pressure sensor is drift free and provides a high-fidelity measurement of blood pressure in coronary arteries. Second, the **EasyWire**, a miniature catheter that slides over existing guide wires to provide a no-drift, highly accurate and reliable measurement of blood pressure in coronary arteries, giving cardiologists the freedom to use their favourite guide wire.

It should be noted that our recently completed animal study demonstrated the good performance of these two products. They delivered good trackability (ability to advance the device through the artery to reach all types of lesions) and optimal pressure.

Opsens intends to maintain a fast development pace that will lead to pre-commercialization by 2012.

### **ISO 13485 Certification**

ISO 13485 certification is an internationally recognized reference standard that incorporates the quality and safety constraints specific to medical devices, such as risk control, traceability and medical device monitoring. By obtaining ISO 13485 certification, Opsens has shown its ability to develop products that are capable of meeting regulatory requirements. ISO 13485 certification is a confirmation from an independent party of the quality of Opsens’ processes with respect to maintaining the industry’s highest standards.

Opsens’ management wishes to thank its dedicated employees for their professionalism that allowed the company to provide its clients with high-quality products. This certification reflects the focus, commitment and passion of our people to ensure the company’s success.

### **About Opsens ([www.opsens.com](http://www.opsens.com))**

Opsens is a leading developer, manufacturer and supplier of a wide range of fiber optic sensors and associated signal conditioners based on proprietary patented and patent pending technologies. Opsens’ sensors provide long-term accuracy and reliability in the harshest environments. Opsens provides sensors to measure pressure, temperature, strain and displacement to original equipment manufacturers (OEM) and end-users in the oil and gas, medical and laboratory fields. Opsens provides complete technical support, including installation, training, after-sales service, for its fiber optics systems that are regulated by the ISO 9001-2008 and ISO 13485 norms.

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