



## **PRESS RELEASE**

*For immediate release*

### **PERCEPTRONIX RECEIVES ISO (International Organization for Standardization) QUALITY CERTIFICATION**

#### ***Critical requirement for obtaining licenses for product sales in Canada and Internationally***

**VANCOUVER, CANADA (July 21, 2005)** – Perceptronix Medical Inc. (“Perceptronix”), a cancer diagnostics medical device company, is proud to announce that it has received ISO 13485:2003 and ISO 9001:2000 certification of its quality management system for the “Design and manufacture of *in vitro* devices for the detection, localization and diagnosis of cancer”. The audit was conducted by the Canadian Medical Devices Conformity Assessment System (CMDCAS) registrar, Intertek Testing Services, NA Ltd., (Coquitlam, BC).

ISO 13485 is required before the medical device market in Canada, the European Union, and several other countries may be accessed. ISO 13485 certification also demonstrates Perceptronix’s commitment to produce medical devices that will consistently meet customer and regulatory requirements. ISO 13485:2003 is the new, internationally recognised quality standard for medical device manufacturers and, although not harmonized with, it is substantially equivalent to, the US Food and Drug Administration’s (FDA) current good manufacturing practises (cGMP).

“While quality is the keystone of all successful products, it is particularly important in the field of medicine. These certifications evidence our commitment to meeting our customers’ needs with products built under continuous quality improvement processes. ISO 13485 certification is also a key requirement for gaining access to the medical device market in Canada and will support the mandatory CE marking of Perceptronix’s products for sale within the EU and several other countries. Our goal is to have our initial products on the market this calendar year. Today’s announcement marks a major milestone on that journey”, said Bojana Turic, MD, Perceptronix’s Vice President and Director of Clinical and Regulatory Affairs.

#### **About Intertek Testing Services, NA Ltd.**

Intertek Systems Certification is the quality management systems certification business unit of Intertek. Intertek was the first accredited certification body in America for ISO 9000, ISO 14001, and among the first QS-9000 approved certification bodies. The Intertek global network consists of over 10,400 staff working out of 254 testing laboratories and 504 inspection offices in 99 countries, including the Intertek Testing Services, NA Ltd. office in Coquitlam, BC.

#### **About ISO**

ISO ([www.iso.org](http://www.iso.org)) is a global network of the national standards institute of 148 countries. The primary objective of ISO 13485:2003 is to facilitate the harmonization of the medical device regulatory requirements for quality management systems.

#### **About Perceptronix Medical Inc.**

Perceptronix ([www.perceptronix.com](http://www.perceptronix.com)) is a private cancer diagnostics medical device company based in Vancouver, Canada. The Company’s goal is to commercialize technologies to improve



the early detection, localization, and diagnosis of cancer, with an initial focus on lung cancer. Perceptronix was founded in June, 1999 to commercialize early cancer detection technologies developed in partnership with the British Columbia Cancer Agency ([www.bccancer.bc.ca](http://www.bccancer.bc.ca)), a world-leader in cancer care and research, with a particularly notable track record in pioneering early cancer detection programs.

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