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China medtech firm gets ISO and CE for PET systems

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Singapore: Neusoft Positron Medical Systems, which is a joint venture between Neusoft Medical Systems and Positron Corporation for the development and manufacturing of positron emission tomography (PET) systems, received ISO certification (9001:2008 & 13485:2003) and CE Mark approval for their Attrius PET Systems.

Based in Shenyang, China, Neusoft Positron Medical Systems has established and applies a quality management system and management system for medical devices in design and development, manufacture, distribution and service of PET scanners.

A CE Mark is a mandatory conformity mark for products placed on the market in the European economic area (EEA). With the CE marking on a product, the manufacturer ensures that the product conforms to the essential requirements of the applicable European conformity (EC) directives. The international organization for standardization (ISO) sets the standards, relating to quality management systems and is designed to help organizations ensure that they meet the needs of customers and other stakeholders, while meeting statutory and regulatory requirements related to the product.

The CE Mark designation will allow Positron Corporation to market, distribute and service the Attrius to the EU and other countries that recognize the CE Mark. At present, the contracting parties to the EEA are the EU and its 27 member, as well as, the three EEA/EFTA states, including Iceland, Liechtenstein and Norway.

While the ISO 9001:2008 certification specifies requirements for a quality management system where an organization needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, the primary objective of ISO 13485:2003 is to facilitate harmonized medical device regulatory requirements for

quality management systems.