

Jubilant gets CE Mark for its medical device and consumable accessories

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This certificate allows the device to be distributed into the European Economic Area (EEA).



Jubilant DraxImage Inc. ("DraxImage"), a wholly owned subsidiary of Jubilant Pharma Limited, is pleased to announce the receipt of the CE Mark certificate for its state-of-the-art RUBY Rubidium Elution System (RbES) and the proprietary RUBY consumable accessories dedicated for use with their RUBY-FILL® (Rubidium Rb82 Generator). This certificate allows the device to be distributed into the European Economic Area (EEA).

The RUBY-FILL® Generator and the RUBY Rubidium Elution System provide the latest technology in Positron Emission Tomography (PET) Myocardial Imaging. RUBY-FILL® is a closed system used to produce personalized patient doses of rubidium (Rb82) chloride injection for intravenous use. Rb82 chloride injection is a radioactive diagnostic agent indicated for PET imaging of the myocardium under rest or pharmacologic stress conditions to evaluate regional myocardial perfusion in adult patients with suspected or existing coronary artery disease.

Jubilant Pharma Senior Vice-President of Medical and Chief Medical Officer Dr. Norman LaFrance stated, "Jubilant DraxImage is extremely excited about the CE Mark certificate, which will provide expanded access of this next-generation PET product into the EEA. With its advanced weight-based dosing accuracy and infusion options, RUBY-FILL will enhance the way patients with known or suspected coronary artery disease are both diagnosed and managed."

"This approval is another landmark event for Jubilant DraxImage, supporting its ongoing commitment to the global expansion and utility of nuclear medicine and PET imaging. Our goal is to grow SPECT and PET imaging globally by providing products that enable physicians to deliver high-quality diagnostic studies as part of our mission of Improving Lives Through Nuclear Medicine," stated Pramod Yadav, CEO Jubilant Pharma LTD.