

HEALTH | INNOVATION | FLUORESCENCE IMAGING | REGULATORY APPROVAL

Fluoptics announces the CE marking of its Fluobeam[®] system

The Grenoble based start-up has also obtained the quality certification ISO 13485

GRENOBLE – Today Fluoptics announces that Fluobeam[®], the company's first fluorescence imaging system, has received its medical CE marking for routine use in cardiac, cardiovascular, hepatic and reconstructive surgeries.

This major step will allow Fluoptics to accelerate penetration of the European market, a major piece of the estimated 2 billion euro global surgical imaging market.

The medical CE ("European Conformity") marking confirms the conformity of a medical device to the quality standards and technical norms of the European Community.

Fluoptics has also obtained the ISO 13485 quality standard, which allow the company to guarantee its European clients a high level of quality in the development and manufacturing of innovative imaging systems and in respect of all regulatory requirements.

Fluoptics CEO, Odile Allard said, *"This dual-certification is an important step in our development and we take it as recognition of the work completed by all of our team. Obtaining the medical CE mark for our first fluorescent imaging system Fluobeam[®], widens the field of applications for our technology and its indications in the operating block. All over Europe surgeons will be able to benefit more widely from Fluoptics' technology."*

The Fluobeam[®] has already been deployed across a range of research applications in over 25 research centres around the world (France, U.S.A., China, Japan, South Korea and Belgium).

About Fluoptics

Created in 2009, Fluoptics is specialized in the development and commercialisation of innovative solutions in fluorescence imaging as a surgical aid. This technology promises a wide range of applications in oncological surgery for the resection of cancerous tumours and the detection of sentinel nodes, but also for cardiovascular, reconstructive and hepatic surgeries. Based at Minatec, in Grenoble, France, Fluoptics employs a staff of 11 with 2011 revenue of 560K €. To find out more visit: www.fluoptics.com

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