



## **Pixium Vision receives ISO 13485 certification for its IRIS<sup>®</sup> and PRIMA Vision Restoration Systems**

- ***A crucial step towards applying for CE mark for IRIS<sup>®</sup>, the company's first Vision Restoration System***

**Paris, France. July 2<sup>nd</sup>, 2014. 7:30 CET** – Pixium Vision (FR0011950641 - PIX), a company developing innovative Vision Restoration Systems (VRS) to allow patients who have lost their sight lead more independent lives, announces that it has received the ISO 13485:2012 certification for the design, development, manufacturing and distribution of its IRIS<sup>®</sup> and PRIMA VRS.

**Bernard Gilly, Executive Chairman and co-founder of Pixium Vision**, said: "We are pleased that the reliability of our quality management system has met the standards of a reference organization. Receiving the ISO 13485 certification enables Pixium Vision to take another important step towards applying for CE mark for IRIS<sup>®</sup>, our first VRS. We remain on track with the development of IRIS<sup>®</sup> and our pre-commercialization activities in line with our plans."

As part of its excellence policy, Pixium Vision set up a quality management system to ensure that its products are inspected and tested by qualified staff at each step of the manufacturing process. The international notified body DEKRA recorded and approved the company's compliance with quality system regulatory requirements, its control of special processes and the risk analysis along the products value chain.

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### **About ISO 13485 standard**

ISO 13485 is a set of standards for measuring the quality of instruments and medical equipment as well as that of medical technologies. These standards define the requirements linked to quality management systems and quality assurance systems related to the design, development, production, installation and maintenance of medical devices. This standard may be used internally or by third parties, particularly certification bodies, to test an organization's ability to answer both regulatory requirements and that of its customers.

### **About Pixium Vision**

Pixium Vision is developing innovative Vision Restoration Systems (VRS) that aim to significantly improve the independence, mobility and quality of life of patients who have lost their sight. Pixium Vision's VRS are composed of various high-tech elements, associated with a surgical intervention as well as a rehabilitation

period. These systems aim to ultimately provide blind patients with vision approaching that of a normal healthy eye.

Clinical trials are currently underway with the VRS IRIS<sup>®</sup> in several centers in Europe. Patients have tolerated their implants well so far and improvements in visual perception have been observed. The results of these studies will be used to apply for CE mark. Commercialization of IRIS<sup>®</sup> is expected to begin in 2015.

Pixium Vision is also developing PRIMA, a subretinal implant currently in preclinical trial. The Company plans to begin clinical trials of PRIMA in Europe in 2016.



Pixium Vision is listed on Euronext (Compartment C) in Paris.  
ISIN: FR0011950641 ; ticker: PIX

IRIS<sup>®</sup> is a trademark of Pixium-Vision SA

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