



Medical robotics specialist Axilum Robotics gets the ISO 13485 certification for its Quality Management System

June 25th 2013, Strasbourg (France) – Axilum Robotics gets the ISO 13485 certification, with Canada extension, for its Quality Management System.

This certification confirms that Axilum Robotics Quality Management System fulfills the requirements applicable in Europe and Canada to companies manufacturing and commercializing medical devices.

Axilum Robotics applies these high level quality requirements in the development and commercialization of its robot for transcranial magnetic stimulation (TMS).

This robot of unique design has been developed specifically for TMS in order to automate this non-invasive, painless brain stimulation technique, currently implemented manually, with a high level of safety and with improved accuracy and repeatability.

There is a growing range of applications for TMS, from neuroscience research to the treatment of neurological and psychiatric disorders such as drug-resistant major depression. TMS has already been approved for the latter in a number of countries and now qualifies for health insurance refunds in the United States.

Axilum Robotics is a spin-off from the ICube¹ Medical Robotics team, and was founded in 2011 by three research professors, Michel de Mathelin, Bernard Bayle and Pierre Renaud, alongside two engineers with PhD in robotics, Benjamin Maurin and Romuald Ginhoux, and Michel Berg, a medical doctor with a degree from HEC business school. Based on an ICube proof of concept, the company began developing a TMS assistance robot with a view to its commercialization. In a fast-growing market, Axilum Robotics' ambition is to become the global leader in robots for TMS.

Two initial TMS centres, Prof. Haffen's Department of Psychiatry at the Besançon University Hospital, France, and Dr. David's team at the Institute of Neurosciences in Grenoble, France, have recently been equipped with Axilum Robotics' robots.

« This certification recognizes the efforts made by Axilum Robotics' team, since the start of the company, with the support of Isocèle Conseil, to implement high level quality procedures, from R&D to customer satisfaction », comments Michel Berg, President and CEO of Axilum Robotics.

« The next step is now to get the Medical CE mark for our robot, also planned for 2013. »

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¹ ICube: Laboratoire des Sciences de l'Ingénieur, de l'Informatique et de l'Imagerie (Laboratory for engineering, computer science and imaging), headed by Michel de Mathelin.

About Axilum Robotics

Axilum Robotics is a spin-off company from the Medical Robotics research team of ICube¹ in Strasbourg (Research Unit of the University of Strasbourg, CNRS, ENGEES and INSA) and has been founded in 2011 by three researchers, two PhDs in robotics and a physician graduated from HEC business school. The company is developing and commercializing a robot to assist researchers and health care professionals with TMS procedures, based on a proof of concept from ICube.

Axilum Robotics is leading a consortium including ICube and the ISO 13485 certified Streb & Weil Company. This project has been certified by Alsace Biovalley life science cluster and has been funded by French Interministerial Unique Fund (FUI), Oséo, Alsace Region, Urban Community of Strasbourg (CuS) and the European Regional Development Fund (ERDF).

End of 2012, Inserm Transfert Initiative, together with scientist and entrepreneur Jacques Lewiner and SODIV Alsace, have jointly invested in Axilum Robotics' project.

www.axilumrobotics.com

¹ ICube for Laboratoire des Sciences de l'Ingénieur, de l'Informatique et de l'Imagerie (Laboratory for engineering, computer science and imaging), headed by Michel de Mathelin.