

Preceyes obtains ISO 13485 certification

Eindhoven, The Netherlands, June 5, 2020 - Preceyes B.V. has received the ISO-EN 13485:2016 certification for its quality management system, effectively obtaining approval for the continued commercialization and production of its CE-marked PRECEYES Surgical System R1.1 under the changing medical regulations.

The PRECEYES Surgical System R1.1 is the world's first CE-marked robot that has been clinically validated to assist surgeons in retinal surgery. The system is developed to assist trained surgeons during vitreoretinal surgical tasks in patients requiring vitreoretinal intervention under local or general anesthesia. The use of the robotic assistant is anticipated to not only improve treatment quality to be provided to patients, it also offers the possibility of developing completely new treatments. The system has a proprietary design and is developed in collaboration with clinicians to user requirements.

The ISO certification ensures to our healthcare providers and patients that Preceyes adheres to quality management and regulatory compliance procedures to develop, manufacture, and test its products and services. The ISO certification recognizes Preceyes' commitment to develop and to commercialize high quality robotic technologies that are recognized as game changers within the field, anticipating to enable new and better treatments, and to standardize, to train and to educate the medical community regarding these technologies in the surgical field. The combination of the CE mark and the ISO certification ensures that Preceyes is prepared for the changing medical regulations and that its robotic system will continue to be available for commercial deployment in Europe for clinical and research activities.

Gerrit Naus, Chief Executive Officer of Preceyes said: "The ISO certification is an important milestone for Preceyes, strengthening Preceyes' position in anticipation of changing medical regulations. We will leverage the certification for further commercial deployment of our products and services in Europe, whilst developing partnerships for accessing markets worldwide."

Further information

Gerrit Naus, Chief Executive Officer of Preceyes B.V., +31-40-247-4789, contact@preceyes.nl. For more information on the PRECEYES Surgical System, visit www.preceyes.nl.

About Preceyes B.V.

Preceyes is a medical robotics company focused on ocular surgery. The company develops, builds and commercializes innovative robotic solutions to assist eye surgeons in performing the most demanding surgical tasks. The company's first target is vitreoretinal surgery. The robot supports the surgeon in improving existing surgery and enables the development of new, high-precision treatments.

www.preceyes.nl