



NEWS RELEASE



For Immediate Release

Si14's Innovative D-EYE Portable Retinal Imaging System Now Registered with EU CE and US FDA

Low-cost alternative to traditional ophthalmoscopy examination is now approved for sale in the US and EU member countries; shipments to begin April 2015

Padova, Italy; Pasadena, CA, USA – January 5, 2015 – Si14, an original design and technology development laboratory, announced today that its innovative [D-EYE Portable Retinal Imaging System](#), a phone-case-sized add-on that turns an iPhone or Android smartphone into a fundus camera capable of taking high-definition video and still images of the eye for health screening and evaluation, is now registered with both the United States Food and Drug Administration and the European CE authority.

The company received US FDA Class 510(K) exempt listing number D231842 on Dec. 19, 2014, and CE Class 1 device registration number 1243284 on Dec. 20, 2014. With CE and FDA registrations, the company is now authorized to sell the D-EYE product in the European Union and the United States. In conjunction with the announcement of these registrations, Si14 stated that it expects to begin shipping the D-EYE Portable Retinal Imaging System in April, 2015.

“We are delighted to receive these FDA and CE registrations, and excited to be able to bring the early diagnosis benefits of D-EYE to patients in the US and Europe,” according to D-EYE CEO Richard Sill. “The D-EYE retinal screening system can be used in any setting by a variety of health professionals ranging from ophthalmologists, optometrists, neurologists, general practitioners, emergency physicians and pediatricians to school nurses, EMTs, and others. The system offers a quick, accurate and inexpensive way to examine the human eye and identify a variety of health conditions, including the leading causes of blindness: glaucoma, diabetic retinopathy and macular degeneration.”

D-EYE is the result of ground-breaking work done by Dr. Andrea Russo, who partnered with Si14 in the development of the device. An ophthalmologist and Ph.D.-candidate researcher with the University of Brescia, Italy, Dr. Russo invented the D-EYE to improve access to vital medical screenings for people in need.

The only truly portable ophthalmoscope capable of digitally imaging the fundus of the eye, the D-EYE device simply attaches to a smartphone (Apple iOS or Android), positioned over the phone's camera lens and LED light source, enabling the phone to capture high-definition video and still images of the interior of the eye. A D-EYE software app installed on the smartphone provides step-by-step instructions, archives all examinations on a patient chart for convenient file management and allows the examiner to email or upload images for review by appropriately trained medical specialists. The soon-to-be-released and HIPAA-compliant D-EYE ImageVault™, a subscription-based cloud platform service, will enable storing and sharing images among medical professionals, promoting telemedicine applications in remote, underserved locations.

The D-EYE Portable Retinal Imaging System offers:

- Complete portability – no power required
- Convenient and ergonomic assessment of bedridden patients and children, even neonatal patients
- Easy viewing of the optic nerve head (even without dilating eye drops) for detecting glaucoma
- Age-related macular degeneration (AMD) screening
- Diabetic retinopathy screening and grading
- Hypertensive retinopathy screening and grading
- Detection of neurological disorders, hemorrhages, arteriolar constriction, blood vessel abnormalities, maculopathy, cotton wool spots, exudates, neuritis, optic neuropathy and other diseases and conditions

Additionally, the D-EYE Portable Retinal Imaging System is an effective tool for veterinarians to use to examine dogs, cats and other small animals to detect glaucoma and other sight-threatening conditions.

For more information about the revolutionary D-EYE Portable Retinal Imaging System, please visit www.d-eyecare.com

About Si14

Si14 is a visionary original design and development laboratory for novel technology products that enhance the way we live, work and play. Founded in 2008 with offices in Padova, Italy, Boston, MA, and Pasadena, CA, USA, Si14 turns inspiration into the realization of compelling, cutting-edge products and services that help people connect with their activities and their world, empower enterprises in realizing greater efficiencies, improve access to vital health screening services for millions worldwide, and much more. An Official Supplier to the Luna Rossa America's Cup Team seeking the sailing world's most coveted prize, Si14 enjoys partnerships with many leading companies and organizations across the technology spectrum, providing Si14 clients with unique insight, experience and access to the latest advances in embedded systems, bio and motion sensing, mobile communications and more. For more information on the D-EYE Portable Retinal Imaging System, please visit www.d-eyecare.com or call 1-626-497-9212 (US) or +39 049 7811 860 (Italy).

#