

## Essilor receives FDA “Breakthrough Device” designation for Essilor Stellest™, its new generation of spectacle lens solutions in the fight against myopia

**(Charenton-le-Pont, 17 May 2021) – Essilor today announced that the U.S. Food and Drug Administration (FDA) has granted “Breakthrough Device” designation to its Essilor Stellest™ spectacle lens, the Company’s new generation lens developed to correct myopia and slow down the progression of myopia in children.**

The designation of the Essilor’s Stellest™ spectacle lens as a “Breakthrough Device” by the FDA, that will lead to further U.S. research and FDA review, builds on the publication of ground-breaking two-year results of an ongoing three-year clinical trial, in China, in myopic children. After the first year, the trial results demonstrated that the eye growth of 9 out of 10 children wearing the Essilor Stellest™ lens was similar or slower than non-myopic children.<sup>1</sup> While after two years, Essilor Stellest™ lens has been proven to be among the most effective myopia control solutions which have ever been tested.

*“The “Breakthrough Device” designation for our Essilor Stellest™ lens is a great achievement and an illustration of its potential in slowing down the progression of myopia in children. This designation represents an important milestone in our fight against the myopia pandemic. We look forward to working closely with the FDA for further clinical study and review, so we can provide the benefit of Essilor Stellest™ to U.S. children who continue to be at risk of vision-threatening complications due to high myopia.”* commented Norbert Gorny, Chief Operating Officer and Chief Research & Development Officer of Essilor International.

The Breakthrough Devices Program by the FDA is intended to provide patients and health care professionals with timely access to medical devices that offer more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions by speeding up their development, assessment, and review.<sup>2</sup>

After successful launch in China and other countries since 2020 with extremely positive response from eye care professionals, Essilor intends to further roll out Essilor Stellest™ in other countries.

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<sup>1</sup> Compared to single vision lenses, when worn at least 12 hours a day. Two-year prospective, controlled, randomized, double-masked clinical trial results - 104 myopic children split in two groups: Single vision lenses (50) and Essilor Stellest™ lenses (54) - Efficacy results are based on 32 children who declared wearing Essilor Stellest™ lenses at least 12 hours per day every day - Eye Hospital of the Wenzhou Medical University - J. Bao, A. Yang, Y. Huang, X. Li, Y Pan, C. Ding, E. W. Lim, J Zheng, D. P. Spiegel, Y. L. Wong, B. Drobe, F. Lu, H. Chen.

<sup>2</sup> <https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program>.

## About Stellest™

The Essilor Stellest™ lens has been designed with an exclusive technology called “H.A.L.T.” technology (Highly Aspherical Lenslet Target) by Essilor’s industry-leading research and development teams. It is the culmination of more than 30 years of academic studies, product design, rigorous research efforts, and collaboration with top research institutes and myopia experts.

The Essilor Stellest™ lens is intended to provide myopia correction and sharp far vision through a single vision zone and myopia control through H.A.L.T. technology. The H.A.L.T. technology consists of a constellation of aspherical lenslets spread on 11 rings and was designed to create for the first time a volume of signal that slows down the elongation of the eye. The power on each ring has been ingeniously determined to guarantee a volume of signal always in front of the retina and following its shape to achieve consistent myopia slowdown.

For more information, visit: <https://www.essilor.com/en/medias/press-releases/with-stellest-lens-essilor-reaffirms-its-leadership-in-myopia-management/>

### About Essilor

*Essilor International is the world’s leading ophthalmic optics company. Essilor designs, manufactures and markets a wide range of lenses to improve and protect eyesight. Its mission is to improve lives by improving sight. To support this mission, Essilor allocates more than €200 million to research and innovation every year, in a commitment to continuously bring new, more effective products to market. Its flagship brands are Varilux®, Crizal®, Transitions®, Eyezen™, Xperio®, Foster Grant®, and Bolon™. It also develops and markets equipment, instruments and services for eyecare professionals. Essilor International is a subsidiary of EssilorLuxottica. For more information, please visit [www.essilor.com](http://www.essilor.com)*

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