

EssilorLuxottica

EssilorLuxottica receives FDA clearance and EU certifications for Nuance Audio, making it available to consumers in the U.S. and Europe

Paris, France (3 February 2025) – EssilorLuxottica announced today that it has received clearance from the Food and Drug Administration (FDA) for its OTC Nuance Audio Glasses. The Group has simultaneously achieved the CE marking under the Medical Devices Regulation in the EU, alongside the development of an ISO Quality Management System certification dedicated to Hearing Aids, which will allow Nuance Audio to launch in Europe.

Paving the way for a disruptive new category in the med-tech space, Nuance Audio Hearing Aid Software is the first FDA cleared, preset Software as Medical Device (SaMD) in the U.S. It delivers a groundbreaking open-ear hearing solution seamlessly integrated into a pair of stylish smart glasses. After decades of adoption barriers ranging from comfort to visibility, consumers will finally be able to see clearly and hear clearly with a single product that is both beautiful and highly functional.

Nuance Audio will be available for purchase in the U.S. beginning in Q1. In the first half of 2025, it will be available in certain European countries, including France, Germany and UK, starting progressively from Italy in Q1, in parallel with U.S. market.

As part of EssilorLuxottica's open business model, the Group will leverage its extensive retail network, while also engaging both traditional audiology practices and optical wholesale customers to make this technology accessible to consumers wherever possible.

"Two years ago, we set out to create a first-of-its-kind product that would change the way people see and hear. We didn't just aim to combine two medical devices – we created an entirely new smart glasses form factor to support the two human senses we depend on the most. It is not only groundbreaking, but also incredibly accessible. We're pleased now to turn our focus to getting this life-changing technology into the hands of people around the world who truly need it," said Francesco Milleri, Chairman and CEO of EssilorLuxottica.

The global hearing solutions market remains underserved, much like the vision market decades ago, where consumers are often hesitant to wear corrective devices due to factors such as stigma, discomfort, cost, and limited accessibility. Nuance Audio seeks to overcome these barriers, which have hindered the widespread adoption of traditional hearing aids. With the introduction of Nuance Audio Glasses, the company aims to meet the needs of approximately 1.25 billion¹ people worldwide who experience mild to moderate hearing loss.

Notes:

¹ World Health Organization, World Report on Hearing, 2021, p. 40.

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About EssilorLuxottica

EssilorLuxottica is a global leader in the design, manufacture and distribution of ophthalmic lenses, frames and sunglasses. With over 200,000 employees across 150 countries, 650 operations facilities and 18,000 stores, in 2023 the Company generated consolidated revenue of Euro 25.4 billion. Its mission is to help people around the world to see more and be more by addressing their evolving vision needs and personal style aspirations. EssilorLuxottica is home to the most advanced lens technologies including Varilux, Stellex and Transitions, the most iconic eyewear brands including Ray-Ban and Oakley, the most desired luxury licensed brands and world-class retailers including LensCrafters and Sunglass Hut. The Company's OneSight EssilorLuxottica Foundation has given access to sustainable vision care to more than 760 million people in underserved communities. The EssilorLuxottica share trades on the Euronext Paris market and is included in the Euro Stoxx 50 and CAC 40 indices. Codes and symbols: ISIN: FR0000121667; Reuters: ESLX.PA; Bloomberg: EL:FP. www.essilorluxottica.com.