

# InnerScope Hearing Technologies Issued Statement About FDA Registration of its Hearing Aids

ROSEVILLE, CA, UNITED STATES, March 27, 2021 /EINPresswire.com/ -- <u>InnerScope</u> Hearing Technologies Inc. (the "Company" or "InnerScope") announced today that it had been made aware that its March 3, 2021 press release regarding the completion of the FDA Medical Device Registration for its hearing aids may have created the misimpression that FDA has reviewed, approved, cleared, or authorized the Company's products.

The Company wants to clarify that as an establishment involved in the production and distribution of medical devices intended for use in the U.S. is required to register annually with the FDA. The Company is also required to register and lists its devices; the resulting entry in FDA's registration and listing database does not denote approval, clearance, or authorization of the Company's facility or its medical devices. Further, the Company's March 3, 2021 press release stating the FDA Registration gives the Company a "clear path for launching its hearing aids" may be construed to be misleading to suggest that the Company obtain an FDA 510(k) clearance for its hearing aids.

## About InnerScope Hearing Technologies

InnerScope Hearing Technologies as a manufacturer, distributor, and retailer of FDA-Registered Direct-to-Consumer ("DTC") App-Controlled Self-Adjusting Hearing Aids, App-Controlled Self-Adjusting Personal Sound Amplifiers Products, Doctor-Formulated Dietary Hearing & Tinnitus Supplements, and Assorted Ear & Hearing Health-Related Products (collectively "Hearing Products") its mission is to improve the quality of life of the 70 million people in North America who suffer from hearing impairment and/or hearing-related issues. The management team of InnerScope is applying decades of industry experience and believes it is well-positioned to directly benefit from the Over the Counter Hearing Aid Act (expected to be enacted in early 2021). InnerScope with its Affordable App-Controlled Self-Adjusting Hearing Technology combined with its innovative point of sale Hearing Screening Kiosks designed for consumers with mild-to-moderate hearing loss to purchase over-the-counter hearing aids without being seen by a hearing care professional. For more information, please visit <a href="https://www.innd.com">www.innd.com</a> for more info.

Please be aware our social media accounts are used from time to time for additional material events.

## https://twitter.com/inndstock

#### Safe Harbor

This news release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended intended to be covered by the "safe harbor" created by those sections. Any statements that are not historical facts contained in this press release are also "forward-looking statements" as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA). Such statements may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning. Such forward-looking statements are based on current expectations, involve known and unknown risks, a reliance on third parties for information, transactions or orders that may be cancelled, and other factors that may cause our actual results, performance or achievements, or developments in our industry, to differ materially from the anticipated results, performance or achievements expressed or implied by such forward-looking statements. Factors that could cause actual results to differ materially from anticipated results include risks and uncertainties related to the fluctuation of global economic conditions, the performance of management and our employees, our ability to obtain financing or maintain contractual relationships with vendors and customers, competition, general economic conditions and other factors that are detailed in our periodic reports filed with the Securities and Exchange Commission ("SEC"). We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA, Securities Act and Securities Exchange Act.

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