

Nuheara achieves international medical device quality certification

PERTH, AUSTRALIA: Medical device and consumer electronics manufacturer Nuheara Limited (**ASX: NUH**) (**Company** or **Nuheara**), is pleased to announce it has been certified to the international standard for Medical device quality ISO 13485:2016. This certification is in addition to the ISO 9001:2015 the Company achieved for non-regulated devices.

This certification is an important next milestone following the Company's recently FDA cleared HP Hearing PRO OTC (over the counter) self-fit hearing aid, which was the world's first OTC self-fit hearing aid to receive FDA clearance. Nuheara's quality management system has been certified by accredited body TÜV SÜD to ISO 13485:2016 for the Design and Development, Production, Distribution of Wireless Air Conduction Hearing Aids.

Commenting on the ISO 13485:2016 quality certification received, Nuheara Co-founder and Managing Director Justin Miller said: "Achieving this is another major milestone for Nuheara on the path of rolling out our US market medical device growth strategy. Receiving this international accreditation is in no small part due to the excellent systems and experience developed by Nuheara's quality team over the past eight years since the Company's establishment."

"Of most significance is the multifaceted certification gained. Our Quality Management System has been audited to the highest medical device standards across Design and Development, Production and Distribution of hearing aids. It's an end-to-end business certification that supports our products' regulatory filings in the US but will also be critical as we expand to include other highly regulated markets globally," added Mr Miller.

ABOUT ISO 13485:2016

ISO 13485 Certified means an organisation has implemented an ISO 13485 Quality Management System and has successfully met all the requirements in ISO 13485. ISO 13485 evaluates whether a Company's Quality Management System is appropriate and effective while emphasising the safety and efficacy of medical devices.

ISO 13485 is a universally acknowledged standard that delivers an effective way to implement quality management and provides a useful structure for business management. It defines the prerequisites for organisations that manufacture, design and or distribute medical devices, ensuring quality in a device's lifecycle and the business processes.

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ABOUT NUHEARA

Nuheara is a global leader in smart hearing technology which change people's lives by enhancing the power to hear. As a global pioneer in Hearable products, Nuheara developed proprietary, multi-functional, personalised intelligent hearing devices that augments a person's hearing. Nuheara is headquartered in Perth, Australia and was the first consumer wearables technology company to be listed on the Australian Securities Exchange (ASX). The Company also has a USA office located in Seattle, Washington.

In 2016, the Company released its revolutionary wireless earbuds, IQbuds, which allow consumers to augment their hearing according to their personal hearing preferences and connect hands free with their voice-enabled smart devices. In 2020 Nuheara released its third-generation hearable the IQbuds² MAX.

In 2021, Nuheara transformed its operations to include medical device manufacturing for its hearing aid products to meet global demand for mild to moderate hearing loss. Nuheara products are now sold Direct to Consumer (DTC) and in major consumer electronics retailers, professional hearing clinics, pharmacies, and speciality retailers around the world.

The Company's mission is to transform the way people hear by creating smart hearing solutions that are both accessible and affordable. For further information, please visit <https://www.nuheara.com/>.