

ASX ANNOUNCEMENT: (ASX:RSH)

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## European CE Mark Approval Received Paving the Way for Successful Partnership Discussions

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Respiri Limited (RSH) is pleased to announce the receipt of the CE Mark (Conformite Europeene) for the next generation AirSonea® at home monitoring device.

- Respiri has received Class IIa CE Mark Approval for its Next Generation AirSonea home monitoring device.
- This approval is integral to partnership discussions providing the ability to market and sell the AirSonea device in the European market, including the United Kingdom (UK).
- The UK is one of Respiri's initial primary target markets and Europe represents one of the three largest markets globally.
- The Class IIa approval is a higher level than the current Class I approval which validates the substantial improvements and advancements made on the AirSonea device software and technology.

Respiri's Chairman, Leon L'Huillier, currently in London, said "The European approval to market AirSonea was important to advance partner discussions. It provides the commercial opportunity to pilot and test market the product from current inventory. This is a significant outcome, allowing for the sale of the devices into the UK and Europe".

### Next Generation AirSonea: Class IIa medical device

The first generation AirSonea technology and software received regulatory approval in the UK, Europe and Australia as a Class I medical device. The world leading, updated AirSonea is a Class IIa medical device and as such, underwent a greater level of assessment by a third party, the Notified Body, to achieve the updated CE Mark.

This assessment and approval is a critical step, which validates the progress made to improve the AirSonea technology to be the world-leading, gold standard in non-invasive, objective monitoring of asthma. It also completes the regulatory approval process to the highest level, allowing Respiri to advance partnership discussions in one of the three biggest medical device markets in the world.

The next generation AirSonea technology update encompasses significant software re-development within both the hardware and the system in its entirety, to provide consumers with an even more effortless, user-friendly, robust and security-compliant objective asthma monitoring and measurement system. Harnessing the processing power of the smartphone, the proprietary acoustic respiratory monitoring (ARM™) technology is now housed in the app, not in the cloud, so patients can measure their wheeze symptom without an Internet connection. Data is then automatically uploaded to the cloud when a WIFI connection is established. Patient data,

including time and date stamped wheeze measurements, medication use and symptoms and triggers are securely stored in the cloud for review by health professionals, who until now, relied on a patient's memory or hand written journals of their asthma management plan. Available over the counter, without doctor's prescription, AirSonea is a symptom measurement tool that provides real-time objective measurement of the primary symptom of asthma, wheezing, and serves as a companion device to new smartphone enabled medication compliance solutions.

Respiri operates in the rapidly evolving field of medical technology with advances in software and technology allowing for the development of medical electronics that are smaller, smarter and more energy efficient. The market for these devices is growing with health conscious consumers now embracing patient self-management and remote monitoring using smartphones, and industry leaders in key markets now recognising that connected mHealth solutions can transform asthma care. Respiri has first-mover advantage in targeting a major unmet consumer need with its primary market of parents and carers of children who cannot perform lung function tests.

Respiri Limited has decades of experience in researching and developing clinical products for hospitals and is one of the few medical device companies, globally, with leading edge technology to participate in the remote monitoring of chronic disease symptoms.

Leon L'Huillier  
Executive Chairman  
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## About Respi Limited

Respi Limited (ASX:RSH) is a medical technology company leading the way in the development of innovative devices and mobile health apps to improve the management of chronic and costly respiratory disorders such as asthma and COPD. Building on decades of experience in the research and development of cutting-edge clinical products for hospitals, the company has first-mover advantage in providing broad access to its proprietary acoustic based clinical solutions for remote monitoring with the development of a suite of over-the-counter connected devices. Health authorities universally agree that mHealth solutions can transform asthma care and health conscious consumers are rapidly embracing patient self-management with the aid of smartphones, the growth engine for Respi's flagship product, AirSonea®. With the addition of new products, including a connected device for nocturnal monitoring in development, Respi has a captive market, globally, of parents and carers of young children who cannot perform lung function tests. Respi products have been cleared for use by the US Food and Drug Administration, the European Union CE, the Australian TGA and the commencement of an approval process for Asian markets has begun.