

ASX Release

Oventus Medical achieves major milestone in global rollout plans - ISO 13485 Certification Granted

Key Points:

- **ISO 13485 certification is a key requirement for the manufacture of Medical Devices for commercialisation in various geographies**
- **Key milestone for the company's global rollout plans**

Brisbane, Australia 10 January 2017: Oventus Medical Limited (ASX: OVN) today announced that its operating subsidiary, Oventus Manufacturing, has received a Certificate of Registration certifying that the Company's Quality Management System complies with the requirements of ISO 13485:20121 for the design, development and manufacture of oral appliances.

The certification was issued by TÜV SÜD, an independent Notified Body. It signifies that Oventus Manufacturing has established a comprehensive quality system that conforms to the International Organization for Standardization (ISO) requirements. The ISO standard is recognized internationally as a universal measure of quality and is a critical prerequisite to securing regulatory approvals in specific geographies.

Oventus Managing Director and Chief Executive Officer, Neil Anderson said "This is an important milestone for our commercialisation path way. Our goal is to provide a commercially available treatment option for sleep apnoea and snoring patients globally, and to introduce innovative diagnostic and monitoring systems in the future. Achievement of ISO 13485 certification reflects Oventus Medical's commitment to the highest level of quality management and to operational and production excellence"

He added: "It is a particular credit to Vanessa Worsfold, our Quality Manager and her team, who have led the process of upgrading the company's systems over the past 12 months. Our commitment to quality across all aspects of our operations including our 3D printing process, remains an important priority as we are about to initiate our US commercial launch, and as we plan for a significant scaling up of our global rollout activities."

ISO13485 is recognised globally as the best quality practice within the medical device industry. Certification is a key requirement for major markets including Europe, the United States of America, Canada, Japan and Australia. Certification demonstrates the organisation's commitment to quality management, and to the provision of safe and effective products that continually meet regulatory and customer expectations.

-ENDS-

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About Oventus

Oventus is a Brisbane based medical device company that is commercialising a suite of oral appliances for the treatment of sleep apnoea and snoring. Unlike other oral appliances, the Oventus devices have a unique and patented airway within the device that delivers air to the back of the mouth bypassing multiple obstructions from the nose, soft palate and tongue. They are particularly designed for the many people that have nasal obstructions and consequently tend to mainly breathe through their mouth. While it may seem counterintuitive, the device actually prevents oral breathing. The O2Vent is designed to allow nasal breathing when the nose is unobstructed, but when obstruction is present, breathing is supplemented via the airways in the appliance.

According to a report published by the Sleep Health Foundation Australia, an estimated 1.5 million Australians suffer with sleep disorders and more than half of these suffer with obstructive sleep apnoea.¹

Continuous positive airway pressure (CPAP) is the most definitive medical therapy for obstructive sleep apnoea, OSA, however many patients have difficulty tolerating CPAP². Oral appliances have emerged as an alternative to CPAP for obstructive sleep apnoea treatment.³

¹ *Deloitte Access Economics. Reawakening Australia: the economic cost of sleep disorders in Australia, 2010. Canberra, Australia.*

² *Beecroft, et al. Oral continuous positive airway pressure for sleep apnea; effectiveness, patient preference, and adherence. Chest 124:2200–2208, 2003*

³ *Sutherland et al. Oral appliance treatment for obstructive sleep apnea: An updated Journal of Clinical Sleep Medicine. February 2014.*