

ASX Release

Oventus Medical receives MDSAP Quality Management Certification

Key Points:

- **Receives Medical Device Single Audit Program (MDSAP) certification for quality management for multiple geographies – including Australia (hence Europe), USA, Canada, Japan and Brazil**
- **This follows recent ISO13485 certification**
- **Certification is a key requirement for the design, development, manufacture and distribution in multiple geographies of Medical Devices**
- **Another key milestone for company's global rollout plans**

Brisbane, Australia, 8th February, 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 MDSAP for the design, development and manufacture of oral appliances. The Medical Device Single Audit Program¹ (MDSAP) certifies the company's quality system for Australia (hence Europe), USA, Canada, Japan and Brazil.

The certification was issued by TUV SUD, an independent Notified Body and follows the company's recent ISO13485² certification.

"This is an important milestone for our commercialisation pathway. 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." said Oventus Medical's Managing Director and CEO, Mr Neil Anderson. "The MDSAP certification ensures we are compliant with quality management requirements for multiple countries and de-risks our recently announced US launch."

1. The Medical Device Single Audit Program (MDSAP) is an international initiative led by Regulatory Authorities (RA) to implement a program where Auditing Organizations (AO) can conduct a single audit of a medical device manufacturer that would be accepted by multiple regulators to address QMS/GMP requirements.
2. 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 management'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.*