

iSonea asthma monitor AirSonea gets CE mark

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Singapore: Australia-based medical technology company iSonea has completed testing and technical documentation for the AirSonea Wheeze Monitor and is all set to receive the Conformit   Europ  enneor CE Mark.

This step clears the way for AirSonea to be marketed in the 27 member states of the European Union, as well as in the four member states of the European Free Trade Association and in Turkey. After thorough testing, the Standards Institute of Israel (SII) and The Electronics and Telematics Laboratory (ETL) have certified that the AirSonea device conforms to the International Organisation for Standardisation (ISO) standards for safety and performance.

The firm has already received several certifications for AirSonea, including International Electrotechnical Commission (IEC) EN 60601-1 (general requirements for basic safety and essential performance of medical electrical equipment); IEC EN 60601-1-2 (electromagnetic compatibility requirements and tests for medical electrical equipment); and European Telecommunications Standards Institute (ETSI) EN 489-1 v1.9.2 (electromagnetic compatibility standards for radio equipment and services), with respect to its safety, performance, and electromagnetic compatibility.

The firm plans to launch the AirSonea Wheeze Monitor in Australia in September 2013 and is assessing market opportunities in the EU for possible entry, following an anticipated 2014 US launch.

"Attainment of these standards of safety and performance allows the Company to complete the technical file and issue a declaration of conformity with the CE," said Mr Michael Thomas, chief executive officer, iSonea. "This is an important step in certifying the product's readiness for sale in key international markets."