

iSonea Achieves CE Mark for AirSonea

iSonea

Medical technology company iSonea Limited has announced that testing and technical documentation has been completed for the AirSonea Wheeze Monitor to receive the Conformité Européenne or 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.

iSonea has received the following ISO safety, performance, and electromagnetic compatibility certificates for AirSonea:

- 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).
- European Telecommunications Standards Institute (ETSI) EN 489-1 v1.9.2 (Electromagnetic compatibility standards for radio equipment and services).

“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 Michael Thomas, chief executive officer. “This is an important step in certifying the product’s readiness for sale in key international markets.”

iSonea 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.

Source URL (retrieved on 01/31/2015 - 11:13pm):

<http://www.mdtmag.com/news/2013/09/isona-achieves-ce-mark-airsona>