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Company Announcements Office  
Australian Securities Exchange

## **CE Mark approval awarded for Nanosonics Ultrasound Disinfecter**

Nanosonics Limited (ASX:NAN) is pleased to announce that it has achieved a major milestone, having been awarded CE Mark for its launch Ultrasound Probe Disinfection device.

This means that the Company is now permitted to manufacture and sell the ultrasound probe disinfecter device in Europe and submit applications to other countries that recognise the CE Mark process, including New Zealand and several Asian and South American countries. In addition, the scope of the approval permits the Company to self-assess product enhancements that may be developed in future. This authorisation to self-assess product improvements is recognition by the certifying body that the Company has developed advanced internal quality control systems and expertise; this level of authorisation is more commonly associated with larger established medical device companies.

The awarding of the CE Mark represents a pivotal event in the Company's development, as it transforms its innovative sterilisation and disinfection technology platform into commercial products targeting substantial global markets.

The Company is now preparing the regulatory file for the Australian authorities (the Therapeutics Goods Administration or "TGA"). There are a number of differences between the requirements for CE Mark and the TGA. It is anticipated that the TGA submission will be lodged in the coming 6-8 weeks.

Later in the year, the more substantial submission for approval by the US Food and Drug Administration (FDA) will be ready for lodgement.

The scale-up of manufacturing will now commence, starting with the letting of contracts for tooling, allowing commercial volume production of the Company's device. The final design now incorporates many improvements over the earlier prototype. Initial product launch is scheduled for late calendar 2008 with manufacturing scale-up to occur in Q1 of calendar 2009.

The awarding of CE Mark also enables the Company to now proceed to finalise various product distribution agreements in Europe and elsewhere and underpins Nanosonics credibility in developing its broader technology pipeline with various potential partners.

Chris Grundy  
Acting CEO

For more information please visit [www.nanosonics.com.au](http://www.nanosonics.com.au) or contact:  
Mr Chris Grundy, Chief Financial Officer, on 61-2-8063 1600.



Nanosonics Limited is developing a portfolio of decontamination products designed to reduce the spread of infection. The Company owns intellectual property relating to a unique disinfection and sterilisation technology which can be suited to a variety of markets.

Initial market applications are designed for the reprocessing of reusable medical instruments. The Company's first product is designed to disinfect Ultrasound Transducers. In parallel with the commercialisation of this product, Nanosonics is also developing other medical applications and exploring opportunities for its proprietary technology in other industries.