ASX ANNOUNCEMENT
20 October 2008

HEARTWARE AWARDED ISO CERTIFICATION

Framingham, MA and Sydney, Australia, 20 October, 2008 - HeartWare Limited (ASX: HTW) today announced that its US based operating subsidiary, HeartWare Inc., has received a Certificate of Registration certifying that the Company's Quality Management System complies with the requirements of ISO 13485:2003.

The certification was issued by BSI Management Systems, the independent Notified Body appointed to assess HeartWare's submission for CE Mark for the HeartWare® Left Ventricular Assist System. It signifies that HeartWare 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 CE Mark and other regulatory approvals.

"This is an important milestone for the Company," said HeartWare's President and CEO, Mr Doug Godshall. "It is a particular credit to Mr Ramon Paz, our Vice president of Quality Assurance and his team, who have led the process of upgrading the Company's systems over the past 18 months. Our commitment to Quality across all aspects of our operations remains an important priority as we move ever closer to our European commercial launch and as we plan for a significant scaling up of our US clinical trial activities."

Following receipt of ISO certification, HeartWare reaffirms its expectation of gaining CE Mark for the HeartWare® Left Ventricular Assist System before the end of 2008.

About HeartWare

HeartWare develops and manufactures miniaturized implantable heart pumps, or Left Ventricular Assist Devices (LVADs), to treat patients suffering from advanced heart failure. The HeartWare® LVAD is the only full-output pump designed to be implanted in the chest, avoiding the abdominal surgery generally required to implant competing devices. HeartWare has completed an international clinical trial for the device involving five investigational centres in Europe and Australia. The device is currently the subject of a 150-patient clinical trial in the United States for a Bridge-to-Transplant indication.

For further information:

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Forward-Looking Statements

This announcement contains forward-looking statements that are based on management's beliefs, assumptions and expectations and on information currently available to management. All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation our expectations with respect to the progress of clinical trials. Management believes that these forward-looking statements are reasonable as and when made. However, you should not place undue reliance on forward-looking statements because they speak only as of the date when made. We do not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. We may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including without limitation those described in "Item 1A. Risk Factors" in our Annual Report on Form 10-K filed with the SEC on February 28, 2008, and those described in other reports filed from time to time with the SEC.