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Ventracor Appoints Notified Body for CE Marking Approval in Europe

Sydney 29 July 2004: Ventracor Limited (ASX:VCR) today announced appointment of the British Standards Institution (BSI) as its notified body for CE marking approval of its "artificial heart" device.

European certification is carried out by a notified body — an organisation nominated by a member government and notified by the European Commission to conduct conformity assessments and approvals for manufactured products sold in the European Union.

Ventracor Limited Chief Executive Officer, Colin Sutton PhD said" Market approval in Europe – the CE mark – will expedite global commercialisation of the VentrAssist™.

"Ventracor's CE mark trial, which will begin soon, is the final step in the product validation process before sale in Europe.

"European certification will give Ventracor access to every country in the European Union – 25 member states with an approximate total population of 450 million people – under one uniform set of product requirements.

"The CE mark is a symbol used to indicate a product meets the legal requirements to allow it to be sold in the EU," Dr Sutton said.

For active implantable medical devices, CE mark is a necessary step before a manufacturer can sell it in Europe.

Ventracor's notified body will examine the VentrAssist™ design and quality system for compliance with all relevant EU directives. The results of the CE clinical trial will also be submitted and data will be assessed against the requirements of the *Active Implantable Medical Devices Directive*.

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CE marking

- In Europe, the letters 'CE' on a manufactured product are a guarantee it meets the essential requirements of the relevant European Drectives.
- For a medical device manufacturer like Ventracor, this is the *Active Implantable Medical Devices Directive (AIMDD) 90/385/EEC.*
- CE marking indicates the product can be legally sold within the European Union (EU) and the European Free Trade Area (EFTA).

Notified Body

- The assessment procedure for CE marking is carried out by a notified body.
- Each EU member government appoints several independent companies to conduct conformity assessments on a range of manufactured products.
- Assessments made by a notified body are recognised by all EU members.
- Notified bodies assess conformity of a product against the conditions set out in the European Union's *New Approach Directives* in support of CE marking.

More information

European Commission: http://europa.eu.int/comm/enterprise/newapproach/

http://www.europa.eu.int/comm/enterprise/medical_devices

Global Harmonisation Task Force: www.ghtf.org

Global Medical Device Nomenclature: www.gmdn.org

British Standards Institution (BSI): www.bsi-global.com

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