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Close up: EC Directive on Active Implantable Medical Devices

The European Community's (EC) Active Implantable Medical Devices Directive (90/385/EEC) will become effective January 1, 1993, covering active (powered) implantable medical devices such as cardiac pacemakers and defibrillators, neural stimulators, and drug infusion devices.

Active implantable medical devices are defined by the directive as any instrument, apparatus, appliance, material or other article, used alone or with accessories or software, intended for use by human beings in the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury; the investigation, replacement or modification of the anatomy or of a physiological process; or the control of conception.

The definition specifies that the devices may be assisted by pharmacological, chemical, immunological or metabolic means, but do not achieve their "principal intended action" by these means. The devices must rely on electrical energy or a source of power other than the human body or gravity. They must be intended to be totally or partially introduced, surgically or medically, into the human body and intended to remain there.

The directive's essential requirements state that these powered implantable medical devices must safeguard the clinical condition and safety of patients, and they must not present any risk to others. The devices must meet safety and efficacy requirements in their design, construction and materials used.

Following an EC type-examination (to establish that they satisfy the directive's requirements), products must bear the "CE" mark in order to be acceptable for distribution throughout the EC and instructions must be provided with the device. In addition, products must be subject to a quality system involving periodic inspections to ensure that they continue meeting requirements.

Further information on the Active Implantable Medical Devices Directive and a listing of European standards it encompasses is available on request from the Standards Council of Canada.

Seminar examines changing rules for selling in Europe

Canadian manufacturers are assured access to Europe's Single Market, says Roger Brockway of the Commission of the European Communities, one of several experts who participated in a seminar entitled *The Rules are Changing -- Standards and Europe 1992*.

In the regulated market, access for non-European products is secured by legislation. In the non-regulated market, he says, "the Community will not interfere in commercial mutual recognition or subcontracting agreements."

The seminar, held December 4, 1990 in Toronto, attracted some 150 business professionals. It was jointly sponsored by External Affairs and International Trade Canada, Ontario's Ministry of Industry, Trade and Technology, the Standards Council of Canada, and the Canadian Exporters' Association.

Under the New Approach to standardization, the Commission of the European Communities issues directives for specific product groups, outlining minimum requirements that must be met before products can circulate freely throughout the EC. Directives already in force (or soon to be) cover toy safety, simple pressure vessels, construction products, electromagnetic compatibility, machine safety, personal protective equipment, non-automatic weighing machines, active implantable medical devices, gas appliances and telecom terminals.

Canadian manufacturers shipping to Europe should identify what directives affect their products, and what standards must be met to satisfy the directives' requirements, says John Kean, President of the Canadian Standards Association. They must also determine what kind of conformity assessment is required,