



## Canada: Health Care - Medical Equipment

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July 09

### Summary

Canada's social health care is best described as a network of ten provincial and three territorial health insurance and healthcare delivery systems. This network of systems ensures all Canadians, residing in the country, have unconditional access to medically necessary hospital/clinical and physician services.

Each provincial or territorial social health system is supported by a network of hospitals, clinics and doctors. Under the prescription of the Canadian Government's legislation, Canada's Health Act, the publicly funded insurance plans of each provinces and territories are required to finance and provide medically necessary care. The extended coverage of each of these plans varies, particularly in the area of services provided outside the hospital or institution's settings, such as outpatient or home health care services recipients.

Canada's health services expenditures for pharmaceutical costs are controlled by a global median price mechanism controlled by government authorities. However, other areas of the health care service industry such as dentistry and optometry remain wholly private.

Canada's health care industry depends heavily on the demand created by the country's publicly funded and insured health care system. It offers American manufacturers of medical equipment, components and supplies excellent sales opportunities. Historically, U.S. medical equipment manufacturers have maintained a significant presence in Canada, not only through distribution export sales, but also with significant manufacturing activities. This trend continues, with U.S. export sales accounting for about 34 percent of the total market or US\$6 billion in 2008. Canada's medical equipment market demand has shifted over the last few years, and while diagnostic and patient monitoring equipment now represent the fastest growing categories, demand for modern and cost-efficient equipment in other categories, such as therapy and surgical equipment, is also growing significantly.

Canadian health institutions' procurement activities account for 80 percent of all medical equipment sales in the country. Canada's total imports of medical equipment were estimated at US\$4 billion for 2008, according to Canadian statistical sources, with U.S. supplier's share of this import market established at about 53 percent.

Large importing distributors and buying groups purchase medical equipment to sell it directly to health facilities. A few large foreign manufacturers still maintain a direct sales force in Canada. However, direct sales are diminishing as distribution proves to be a more cost effective strategy, particularly for the smaller players.

Local manufacturing of medical equipment is also a source of export opportunities for U.S. suppliers of components. None of the Canadian manufacturers dominate the local market in any specific category but they tend to be very successful exporters. Large U.S. corporations, including GE, 3M, Bard, Baxter, GE, McKesson and Medtronic are the dominant manufacturers.

The use of medical equipment is strictly regulated in Canada. Health Canada's Therapeutic Products Program (TPP) ensures the safety and effectiveness of such equipment. Canadian authorities have also worked at harmonizing their regulations with those of Europe and the United States. Medical devices are classified into four categories depending on the level of potential risk to the patient. Class I represents devices that pose the least risk while Class IV devices pose the highest risk.

## Market Demand

### Canada's Socialized Medicine System

Canada's health care industry is based on the country's publicly funded and insured health care system. This system is an interlocking set of ten provincial and three territorial health insurance plans and healthcare delivery programs. Known to Canadians as "Medicare", this network of provincial and territorial healthcare systems provides all Canadians access to a comprehensive coverage for medically necessary hospital/clinical and physician services.

Each provincial or territorial social health system is supported by a network of hospitals financed by taxpayer funds. This network ultimately report to the provincial and territorial government health ministry. However, each hospital's operations are controlled by private boards and/or regional health authorities. Interestingly, most physicians in Canada are self-employed. They are not employees of the government nor are they accountable to the government other than for the service fee claims they submit to a single provincial or territorial health care plan for reimbursement. More than 90 percent of these doctors are paid on a fee-for-service basis.

Under the terms of the Canadian Federal Government's Health Act, prescribing what essential health care services should be provided to all Canadians, the provincial or territorial publicly funded insurance plans are required to finance and provide medically necessary care. This care must be delivered in hospitals or clinics by physicians registered with the system. It is also important to note that there are variations among provinces/territories as to which costs, particularly as outpatient, are covered. These may or may not include prescription drugs, physical therapy, long-term care, home care, dental care and even ambulance services.

Canada's system is known as a single payer system, where basic services are provided by private doctors (since 2002 they have been allowed to incorporate), with the government paying the entire fee at specified rate. Most family doctors receive a fee per visit and an additional fee for each individual medical act. These rates are negotiated between the provincial governments and the province's medical associations, usually on an annual basis. Unless a physician opts out of billing the publicly funded system altogether, he or she cannot charge a fee for a service that is higher than the negotiated rate — even to patients who are not covered by the publicly funded system.

Similarly, in Canada, the government sets pharmaceutical costs at a global median price. Federal and provincial governments have a major role in drug prices regulation. Prescription drug prices are subject to direct control by the Patented Medicine Prices Review Board (PMPRB), a government agency, under the banner of the Federal Health Department of Canada. Created under the Patent Act of Canada. Prices of drugs set by manufacturers are limited for all patented medicines, whether or not they are available by prescription or over-the-counter. The PMPRB acts as an independent, quasi-judicial tribunal. It is considered to have both a regulatory role, as it ensures that consumers can access their medications at a reasonable price, but it also acts as a reporting agency, by monitoring R&D spending and pharmaceutical trends. However, even though the PMPRB has no authority over unpatented medicines, and therefore does not regulate prices of generic drugs, there is a possibility that the board's jurisdiction could be broadened to regulate non-patented drugs prices, which would require provincial cooperation.

Many factors come into consideration when it comes to set the price of a patented drug. For instance, when it comes to fixing the price of a new drug, two main factors are considered. First, the price of that drug is compared to that of the existing drugs used for a similar treatment. Second, the price of that drug is not to exceed the median price of a certain group of industrialized countries (France, Germany, Italy, Sweden, Switzerland, United Kingdom and United States). When it comes to existing drugs, their prices cannot increase by more than the Consumer Price Index (CPI), on an annual basis. Given that inflation is currently at a rate of about 2.5%, which will likely decline in the coming months, and that keeping inflation under control continues to be a cornerstone of Canadian fiscal and monetary policy, it is unlikely that drug prices would exceed increases of 2.5%

In other areas of the health care service industry which are recognized as being wholly private, such as dentistry and optometry, professional associations set the fees for services rendered. Fees in dentistry are established by provincial chapters of professional associations in dentistry. For example, the "Association des chirurgiens dentistes du Québec" publishes an annual reference guide entitled Fee Guide and Description of Dental Treatment Services to help dentists establish a fee structure for dental services performed under normal conditions. The guide is available from the National Library of Quebec. The fees for dental care vary from one dental practice to another. They are based on a number of factors, particularly the complexity and level of difficulty of the treatment and the type of technology used. Dentists are obligated to explain the treatment plan and costs to their patients and get their consent before beginning any treatment.

For the optometrists in Canada, diagnostic services are mostly covered by and negotiated with the provincial health care plan concerning children and seniors. It is seen as an extension of Medicare. In Ontario, the government will pay over \$40 to evaluate a child, and nearly \$50 for a senior. Seniors, however, are also covered for other billings at the time of a visit and practitioners can tandem bill for diagnostic services not covered under the public health plan (eg. retinal photography). So by the time a senior finishes with their visit, the reimbursement to the practitioner can be over \$100.

For patients not covered by the provincial health plan (eg. those b/w 20-64 yrs of age), optometrists charge privately for a visit using their association's fee schedule, which in Ontario recommends over \$100/visit, depending on the complexity of the service rendered. All billings to the provincial health plan are submitted electronically and paid within approx 45 days. Eyewear is not covered by the government health plan, unless a patient is registered as indigent.

Considering the universality and range of health care services provided to all Canadians, Canada's total healthcare expenditures fair well against those of comparable highly developed countries. However, healthcare expenditures in Canada continue to grow at a rate expected to exceed 5 percent in the foreseeable future while dollars spent shift categories indicating changes in trends worth identifying. In 2008, public and private sector expenditures on healthcare in Canada was estimated at about US\$150 billion, representing an estimated 10.7% of Canada's GDP. Private sector expenditures (outside the Medicare coverage) are foreseen to increase faster than public sector, namely in dentistry and optometry. Opportunities for U.S. exporters exist in both sectors.

### **Trends and Factors Influencing Demand for Medical Equipment**

In 2004 the First Minister's Meeting on the Future of Health Care developed a ten-year plan which emphasized investments in health system innovation through science, technology and research. Recognizing the progress that has been made, the federal government committed to continued investments to sustain activities in support of health innovation. As a result, the demand for diagnostic and patient monitoring equipment has grown, stimulating sales of medical equipment over the past four years. This trend should continue through 2010. The increase in demand for all types of electro medical equipment will be led by technologies including MRI (magnetic resonance imaging) and CT (computed tomography). Other medical electro-diagnostic and patient monitoring equipment, including ultraviolet and ultrasonic scanners should also benefit from increased demand. The average real growth of Canadian demand value for all medical equipment and supplies during the 2009 and 2010 period should remain strong because of already committed annual budget increases of between 8 and 9 percent.

Import activities are reflective of that demand trend and the following table which illustrates the progression of Canadian imports of the most popular categories of medical imaging and diagnostic equipment in the past five years.

<b>Products</b>	<b>2004</b>	<b>2005</b>	<b>2006</b>	<b>2007</b>	<b>2008</b>
<b>HS 901820 – ULTRAVIOLET OR INFRARED RAY APPARATUS</b>	3.27	5.22	9.28	9.89	10.77
<b>HS 901812 – 1ULTRASONIC SCANNING APPARATUS</b>	3.30	4.30	5.13	5.48	5.22
<b>HS 902212 – X-RAYS COMPUTED TOMOGRAPHY APPARATUS</b>	2.94	6.26	4.52	3.53	4.70
<b>HS 901813 – MAGNETIC RESONANCE IMAGING APPARATUS</b>	2.84	3.77	2.30	3.65	3.96
<b>HS 901819 – OTHER MEDICAL ELECTRO-DIAGNOSTIC AND PATIENT MONITORING APPARATUS NES</b>	1.63	1.77	1.86	2.13	2.37

Millions of US Dollars

One particular equipment area which falls under the category of, “Other Medical Electro-Diagnostic and Patient Monitoring Apparatus,” is that of sleep labs. According to an industry source, nighttime neurological monitoring devices have experienced an increase in popularity over the last year. This is a driving factor behind the growth in demand of the category under HS 901819. Another specific product which has experienced a similar rise in demand is HS 9018199013, Electroencephalographs (EEG) and electro-myographs (EMG). Since 2004 these monitoring and diagnostic products have experienced an average annual growth rate of 17%, with import value peaking in 2007 at US\$2.2 million.

Another area which is expected to see a rise in demand is the Canadian medical waste treatment and disposal equipment market, which should grow significantly over the next five to ten years. As national legislation imposes more infection safe and environmental controls in the delivery of health care services for increasingly environmentally minded Canadians, the Government of Canada (GOC) is placing a strong emphasis on procurement of cost effective medical waste treatment and disposal equipment that reduces environmental contamination and pollution in the long term. This investment effort opens significant opportunities for other non-polluting technologies and equipment that will help reduce emissions and serve to advance higher environmental standards. The [Canadian Standards Association](#) and [Environment Canada](#) set the standards and regulations for the disposal of hazardous and medical waste materials; and, offer guidelines that will be of interest to U.S. suppliers looking at entering the Canadian marketplace.

Another development that will provide opportunities for U.S. companies is in the province of Quebec, is the construction of Montreal’s new University Hospital Center also known under the acronym of CHUM. Estimated at US\$ 1.5 billion, the project is clear to move forward in a public-private partnership agreement that should be signed in 2010. Its construction should be under way in 2010 with completion of phase 1 by 2013 and phase 2 by 2017. This university hospital center is a project that will create excellent export opportunities for American firms providing not only medical equipment but also those offering other products and services that such a project entails, including ITs. Immediate positioning for representation is therefore important, if not crucial.

## Market Data

### Canadian Market Medical Equipment (In US\$ millions)

	2007	2008	2009 (projected)	Avg. Ann. Growth 2009-2010
Total Market Size	5586	6124	6651	(10.6%)
Total Local Production	2729	2960	3167	(10.5%)
Total Exports	768	860	942	(9.5%)
Total Imports	3625	4024	4426	(10.5%)
Imports from the U.S.	1991	2185	2349	(9.5%)

### Imports

American suppliers' share of Canadian imports has decreased slightly over the last few years. However, more than half of Canadian imports continue to originate from the United States. Germany, China, and Japan respectively follow as countries of origin in Canadian imports statistics reflecting a combined share of about one fifth of total Canadian imports. While imports from U.S. sources are projected to grow between 7 and 8 percent annually in 2009 and 2010, imports from Germany, China, and Japan should continue to outgrow U.S. imports with rates of between 10 and 20 percent per annum.

### Local Production

As part of total imports figures reflecting the trade of medical equipment and parts, there is a demand for components shipped to local manufacturers. This demand is generated by the activities of Canadian medical equipment and devices manufacturers that are established in all parts of the country and specialize in the design, development and fabrication of a variety of products. These include electro medical equipment and related software, furniture, supplies and consumables, orthopedic appliances, prosthetics, as well as diagnostic kits, reagents, and other diagnostic equipment. These Canadian manufacturers are potential clients to U.S. suppliers of components and parts. Here is a quick Canadian manufacturing country tour.

From East to West, Canada is home to medical device manufacturing activities. Canadian manufacturers excel in cardiovascular devices with firms like Vancouver's Neovasc, Greater Toronto's Novadaq Technologies, and Montreal-based CryoCath Technologies (acquired by Medtronic in 2008).

On the Atlantic shore, Halifax's technology cluster developers have invested more than \$100 million into research led by universities, colleges, hospitals and government labs engaged in life-sciences work enticing leading medical device manufacturers to produce innovative products. Halifax based firms, such as MedMira Laboratories, specialize in in-vitro diagnostics while Eastmed produces devices that cater specifically to female patients and St. Andrew's cross is developing medical surgical devices.

Montreal, Canada's second largest city and the heart of Quebec's economy, is home to cutting-edge companies such as Art, Noveko International, Orthosoft (acquired by U.S. Zimmer) and Resonant Medical. Advanced Research Technologies' SoftScan® breast cancer diagnostic tool and Clemex Technologies' world-renowned image analysis tools contribute to Canada's medical manufacturing's reputation for innovation.

Toronto, Canada's largest city with a metro population exceeding 5 million is home to the MaRs Centre, a gateway to Canada's largest concentration of scientific research, anchored by major teaching hospitals, the University of Toronto and more than two dozen affiliated research institutes. The city hosts subsidiaries of major multinational medical device firms specializing in medical imaging, robotics and e-health. Among these firms are reputable names like 3M, Abbott Point-of-Care, Bard, Baxter Corporation, Best Medical, GE Healthcare, Johnson & Johnson, McKesson and Medtronic-CryoCath Technologies, Siemens Medical Solutions, St. Jude Medical Canada Inc., Sorin Group and Zimmer-Orthosoft,

The city of Winnipeg, Manitoba, leads research into MRI and other non-invasive surgical technologies conducted at the National Research Council Institute for Biodiagnostics, Canada's most advanced facility for magnetic resonance technologies, and at the St. Boniface General Hospital Research Centre. Foremost firms in the area include IMRIS Inc., a global leader in the supply of fully integrated, intra-operative imaging systems and Intelligent Hospital Systems Inc., which designs and develops automated solutions for hospitals.

Edmonton, Alberta and the surrounding region host globally-recognized researchers and state-of-the-art facilities that provide a wealth of biomedical research capacity. The universities of Alberta, Calgary and Lethbridge, focus on primary research, including the National Institute for Nanotechnology and the National Research Council Institute for Biodiagnostics West. The area's medical devices sector is renowned for wound care, personal protective equipment, medical diagnostics and medical imaging technologies. Calgary's Imaging Dynamics is a leader in digital radiography, with its imaging system being used in nearly 40 countries worldwide.

Vancouver's medical device manufacturing and distributing companies specialize in interventional and implantable cardiology, diagnostic and therapeutic ultrasound, diagnostic testing and analysis, as well as orthopedic and device design and development. Investments of \$1.5 billion in science infrastructure in recent years, including major investments in R&D, enhance the sector's success. Simon Fraser University's 4D labs support the cluster through its research on advanced materials and nanoscale devices. Vancouver region's Response Biomedical Corp. has formed strategic alliances with 3M Company and with Roche Diagnostics to commercialize its diagnostic tests in various parts of the world.

The local production of medical devices is relatively significant in Canada and increasingly depends on exports, which are primarily shipped to the U.S. and other markets. Larger manufacturers operating in Canada tend to be foreign-owned while Canadian-owned firms are more niche and specialty market oriented. The following is a list of the most representative names in the two categories.

#### **Foreign-Owned – Multinationals**

- [3M](#)
- [Abbott Point-of-Care](#)
- [Bard](#)
- [Baxter Corporation](#)
- [Best Medical](#)
- [GE Healthcare](#)
- [Johnson & Johnson](#)
- [McKesson](#)
- [Medtronic-CryoCath Technologies](#)
- [Philips Medical Systems](#)
- [Roche Diagnostics](#)
- [Siemens Medical Solutions](#)
- [St. Jude Medical Canada Inc.](#)
- [Sorin Group](#)

- [Thermo Fisher Scientific](#)
- [Zimmer-Orthosoft](#)

#### **Leading Canadian companies**

- [ART Advanced Research Technologies](#)
- [Axela](#)
- [BioMedica Diagnostics Inc.](#)
- [BioSyntech](#)
- [Clemex Technologies](#)
- [DNA Genotek](#)
- [Epocal](#)
- [GeneNews\(TM\) Ltd.](#)
- [Imaging Dynamics](#)
- [IND Diagnostic Inc.](#)
- [MDS Nordion](#)
- [MedMira Technologies](#)
- [MIV Therapeutics](#)
- [Neovasc](#)
- [Novadaq Technologies](#)
- [Noveko International](#)
- [Orthosoft](#)
- [Pyng Medical](#)
- [Resonant Medical](#)
- [Response Biomedical](#)
- [Spectral Diagnostic](#)
- [Urodynamix Technologies Ltd.](#)

#### **Best Prospects**

Demand for diagnostic equipment will lead the growth in sales of medical equipment over the next two years in Canada, 2009-2010. The increase in demand for medical and diagnostic equipment will be led by technologies including nuclear medicine cameras, MRI (magnetic resonance imaging) and CT (computed tomography). Other medical electro-diagnostic and patient monitoring equipment, including ultraviolet or infrared rays and ultrasonic scanners will also be subjected to an increased demand. However, the average real growth of Canadian demand value for all medical equipment and supplies during the 2009 and 2010 period should be moderate at between 4 and 6 percent annually.

#### **Best Products/Services by HS Code**

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- HS 901812 - Ultrasonic Scanning
- HS 901813 - Magnetic Resonance Imaging
- HS 904819 - Other Medical Electro-Diagnostic and Patient Monitoring
- HS 901820 - Ultraviolet and Infrared

## HS 902212 - X-Ray Equipment Computed Tomography

### Prospective Buyers

Hospitals and other public health institutions are the principal purchasers of medical equipment and supplies, accounting for about 70 percent of the total market demand in Canada. They tend to buy directly from manufacturers for capital equipment and tend to utilize group procurement and distribution for regular medical equipment including devices, instruments and supplies

On the private side, demand for imaging diagnostic equipment is also favorable with privately-owned clinics and other establishments and should grow at a slightly higher rate than the overall market in 2009 and 2010.

One of the more well-known group purchasing organizations of health care equipment in Canada is MedBuy, a firm who now represents 35 per cent of the country's healthcare facilities. In 2007, Medbuy's contract purchases for products and services totaled more than US\$500 million through its Medical/Surgical and Pharmacy purchasing programs. Med Buy works on behalf of 43 members such as health authorities and hospital organizations that represent more than 350 healthcare facilities in British Columbia, New Brunswick, Nova Scotia and Ontario.

### Market Entry

#### Regulations

The sale and use of medical devices is strictly regulated in Canada by an FDA equivalent called Health Canada. Health Canada's [Therapeutic Products Program \(TPP\)](#) ensures the safety and effectiveness of medical devices. TPP comprises several bureaus that regulate pharmaceuticals, blood, biologic's, disinfectants and medical devices. The Bureau is responsible for processing device license applications, reviewing the safety and effectiveness data for various devices, establishing standards and policies for medical devices as well as addressing related issues regarding the safety of medical devices. The TPP web site contains documents that may be downloaded including the Medical Devices Regulations, Guidance Documents, Policy Documents, Information Letters, Alerts, and other information for manufacturers to keep abreast of regulatory requirements.

Similarly to FDA, medical products or devices are classified into four categories depending on the level of potential risk to the patient. Class I represents devices that pose the least risk while Class IV pose the highest risk. Licenses are delivered for each product or category of product in Class II, III and IV. Determination of risk class is based on a set of rules contained within the regulations. Each rule defines how a device is classified based on how it is used, whether it is invasive, the system of the body it primarily affects and whether energy, (electrical or other), may be transferred in a potentially hazardous way.

This system of rules is referred to as a Ruled Based Set of Regulations and a Risk Based Classification System. In-vitro diagnostic devices are classified separately from medical devices but are nevertheless classified into one of four risk classes. Medical devices may be arranged into families, groups, group families or systems for purposes of obtaining a medical device license.

The manufacturer of a Class II, III or IV medical device must obtain a device license before the product may be sold on the Canadian market. The requirements for obtaining a device license vary according to the risk classification of the device. The exception is for Class I devices, which do not require a license, although they are still subject to the safety and effectiveness requirements of the Regulations. Class II device license applications are fairly straightforward and require basic information. Class III and IV applications are more involved and require the submission of more substantial information to support the safety and effectiveness requirements.

Under the Food and Drugs Act, Health Canada defines a medical device as: any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals, storing, correcting or modifying a body function or the body structure of human beings or animals; the diagnosis of pregnancy in human beings or animals, or the care of human beings or animals during pregnancy and at and after birth of the offspring, including care of the offspring; and includes a contraceptive device but does not include a drug.

Canada's regulations require the manufacturer of a medical device to satisfy 11 safety and effectiveness requirements based on objective evidence to establish that a medical device satisfies those requirements. In addition, a medical device must bear a label that contains specific information as described in the Regulations.

Electrically powered equipment imported into Canada must comply with Canadian standards for such products. Accredited by the Standards Council of Canada, the Canadian Standards Association (CSA) is Canada's standard-setting entity for electrically powered products. However, Underwriter's Laboratories (UL), the largest safety testing and certification organization in the United States, also carries accreditation from the Standards Council of Canada. As a result, UL's certification acceptance in Canada, recognized under the "C-UL" mark in all ten provinces, can translate into savings for U.S. manufacturers seeking product standard approval for both Canadian and U.S. markets. Information pertaining to product certification can be obtained by contacting the CSA or the UL directly (see Key Contacts section).

Health Canada requires suppliers to provide test evidence indicating the safety and effectiveness of the equipment within ten days of entry into Canada. Medical equipment imports must also comply with marking, labeling and packaging requirements according to the applicable section of the Canadian Food and Drug Act, entitled "Medical Devices Regulations". In order to facilitate the entry of U.S.-made health care equipment into Canada, instructions (operator's manual) accompanying the equipment should be in both of Canada's official languages, English and French, and should comply with Canadian packaging and labeling requirements as prescribed by Industry Canada.

### **Distribution**

The selection of a national distributor with well-defined provincial and regional strategies and resources is essential in an increasingly competitive and changing Canadian market. End-user outreach programs, as well as the existence of service and technical support organizations inherent to the business of selling home care and mobility equipment, require established, reliable and knowledgeable dealers willing to offer their service and loyalty, to ensure effective market penetration.

## **Market Issues & Obstacles**

Partnering with the various provincial health authorities responsible for the delivery of essential health care services for all Canadians throughout the country is essential to the success of the commercialization of advanced medical equipment. Advanced technology is often regarded as the ultimate solution to facing the growing demand for better healthcare care and its cost efficient delivery. One prime recent example of this type of partnering is with the Canadian division of McKesson Corporation, McKesson Canada.

McKesson Canada, through its health information technology division, Integrated Healthcare Solutions, has led a consortium to build one of the largest diagnostic imaging repository (DI-r) in North America. McKesson Canada will provide picture archiving and communication system (PACS) - plus related services and maintenance to 43 hospital facilities within the Quebec regions of the Réseau universitaire intégré de santé McGill University and Réseau universitaire intégré de santé de l'Université de Montréal (RUIS McGill and RUIS Montréal university-affiliated hospital groups). These 43 health facilities serve 60% of Quebec's population of 7.5 million.

The Canadian medical equipment market presents a number of advantages to foreign manufacturers, especially U.S. firms. U.S. firms benefit from a general similarity between U.S. and Canadian regulations concerning the safety and quality of medical devices, as well as close geographic proximity to Canada. The similarities in general business practices also help to facilitate distribution and trade activities. U.S. manufacturers enjoy a good, long-established reputation in Canada. U.S.-made medical equipment is typically known for its quality, reliability and advanced technology.

## Trade Events

Health Achieve Conference and Exhibition  
Organized by Ontario Hospital Association  
November 16, 17 & 18 Metro Toronto Convention Centre  
Contact: Isabella Wai - 416-205-1354  
Email: [iwai@oha.com](mailto:iwai@oha.com)  
Website: [www.ohahealthachieve.com](http://www.ohahealthachieve.com)

Health Achieve is the largest health care gathering in Canada. It provides a conference program with educational sessions along with an exhibition floor hosting 350 exhibitors showcasing health care products, services and technologies.

Health Achieve attracts annually about 9,000 delegates including chief executive officers, trustees and representatives from a broad range of administrative and clinical areas such as: diagnostic services, purchasing, finance, human resources, infection control, information technology and nursing.

## Resources & Contacts

Health Canada  
Therapeutic Products Directorate  
Medical Devices Bureau  
Building 3, Tunney's Pasture  
Address Locator: 0301H1  
Ottawa ON K1A 0K9  
Phone: (613) 957-1909  
Fax: (613) 957-6345  
Email: [device\\_licensing@hc-sc.gc.ca](mailto:device_licensing@hc-sc.gc.ca)  
Website: [www.healthcanada.gc.ca/medicaldevices](http://www.healthcanada.gc.ca/medicaldevices)

Canadian Standards Association  
5060 Spectrum Way, Suite 100  
Mississauga, ON L4W 5N6  
Phone: (416) 747-4044  
Fax: (416) 747-2510  
<http://www.csa.ca>  
<http://www.shopcsa.ca/onlinestore/GetCatalogItemDetails.asp?mat=2416708>

Underwriter's Laboratories  
333 Pfingstein Road  
Northbrook, Illinois  
60062  
Tel: (847) 272-8800  
Fax: (847) 272-8129  
Contact: Ms. Francine Taylor, Client Advisor  
<http://www.ul.com>

### List of medical device license registrars provided by Health Canada

These registrars are recognized under section 32.1 of Canada's Medical Devices Regulations and authorized to issue quality certificates for: CAN/CSA ISO 134885:2003 and ISO 13485:2003

BSI America, Inc.

12110 Sunset Hills Road, Suite 200, Reston, Virginia, 20190-3231 USA

Phone: 800 862-4977 (Canada & USA only) 703 437-9000 - Fax: 703 437-9001

E-mail: [inquiry@bsiamericas.com](mailto:inquiry@bsiamericas.com)

Web site: <http://www.bsiamericas.com>

DQS GmbH

August-Shanz-Strasse 21, Frankfurt am Main D-60433 Germany

Phone: 49 69 9 54 27 372 - Fax: 49 69 9 54 27 212

E-mail: [dqs.zentrale@dqs.de](mailto:dqs.zentrale@dqs.de)

Web site: <http://www.dqs.de>

Intertek Testing Services North America Ltd. (ITS)

1829 32nd Avenue, Lachine, Québec, H8T 3J1 Canada

Phone: 514 631-3100 - Fax: 514 631-1133

E-mail: [intertek-sc@intertek.com](mailto:intertek-sc@intertek.com)

Web site: <http://www.intertek-sc.com>

KEMA Registered Quality, Inc.

4377 County Line Rd., Suite 202 - Chalfont, Pennsylvania, 18914 USA

Phone: 215 997-4519 - Fax: 215 997-3810

E-mail: [info@krqusa.com](mailto:info@krqusa.com)

Web site: <http://www.krqusa.com>

Laboratoire national de metrologie et d'essais, division certification G-MED

1, rue Gaston Boissier, 75724 Paris CEDEX 15 France

Phone: 33 1 40 43 39 72 - Fax: 33 1 40 43 37 37

E-mail: [corinne.delorme@lne.fr](mailto:corinne.delorme@lne.fr)

Web site: <http://www.gmed.fr>

LGA Intercert GmbH

Tillystrasse 2 D-90431, Nuremberg Germany

Phone: 49 911 6 55 41 61 - Fax: 49 911 6 55 41 70

E-mail: [intercert@lga.de](mailto:intercert@lga.de)

Web site: <http://www.lga-intercert.com>

Lloyds Register Quality Assurance (LRQA)

1401 Enclave Parkway, Suite 200, Houston, Texas, 77077 USA

Phone: 281 398-7370 - Fax: 281 398-7337

E-mail: [marketing-usa@lrqa.com](mailto:marketing-usa@lrqa.com)

Web site: <http://www.lrqausa.com>

National Standards Authority of Ireland (NSAI)

1 Swift Square, Northwood, Santry, Dublin 9, Republic of Ireland

Phone: 353 1 807 3800 - Fax: 353 1 807 3844

E-mail: [medical.devices@nsai.ie](mailto:medical.devices@nsai.ie)

Web site: <http://www.nsai.ie>

SAI Global Certification Services Pty Ltd.  
286 Sussex Street, Sydney, NSW 2000 Australia  
Phone: 416-401-8700, 800-465-3717 - Fax: 416-401-8650  
E-mail: [malcolm.phipps@qmi-saiglobal.com](mailto:malcolm.phipps@qmi-saiglobal.com)  
Web Site: <http://www.saiglobal.com>

SGS United Kingdom Ltd.  
Inward Way, Rossmore Road, Ellesmere Port, Cheshire CH65 3EN UK  
Phone: +44 (0) 1934 522917 - Fax: +44 (0) 1934 522137  
E-mail: [sgsprodcert@sgs.com](mailto:sgsprodcert@sgs.com)  
Web site: <http://www.uk.sgs.com>

TUV Rheinland of North America, Inc. - North American Headquarters  
12 Commerce Road. Newtown , Connecticut , 06470 USA  
Phone: 888 743-4652 (Canada & USA only) 203 426-0888 Fax: 203 426-4009  
E-mail: [info@tuv.com](mailto:info@tuv.com)  
Web site: <http://www.us.tuv.com>

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