

**MEDICAL DEVICES MARKET OPPORTUNITIES
FOR U.S. SMALL AND MEDIUM-SIZED ENTERPRISES**

ExportMED Brazil

U.S. DEPARTMENT OF COMMERCE
International Trade Administration
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Office of Microelectronics, Medical Equipment
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PREFACE

This report – the first in a planned series of ExportMED reports on developing markets - describes and analyzes trends, key issues, and events in Brazil's medical devices sector, to assist U.S. small- and medium-sized enterprises (SMEs) in making educated business decisions about entering that market. The report examines the medical devices industries, including its domestic medical devices and diagnostics market and the best market opportunities and sales prospects for U.S. SMEs. The report also considers economic, cultural, and political factors influencing Brazil's medical devices market. Finally, the report provides information on market entry requirements and strategies for SMEs, and U.S. Department of Commerce and other resources to help U.S. firms in their market entry endeavors. Appendices list useful contacts in the United States and Brazil, as well as recent statistics for medical devices exports to Brazil and further information about Brazilian medical devices associations.

The medical devices covered in this report include (as classified under the North American Industrial Classification System – NAICS) electromedical equipment (334510), irradiation (x-ray) apparatus (334517), surgical and medical instruments (339112), surgical and medical supplies (339113), and dental equipment (339114). While an effort was made to harmonize data from sources in Brazil, the United States, and elsewhere, differences in product classification systems and statistical reporting methods make some inconsistencies unavoidable. The market, production, and trade data presented here are in U.S. dollars except as noted in the text.

This report is based on market research and analysis undertaken in Brazil in 2002-03, including several trips by the OMMI Director Jeffrey Gren, Medical Devices Team Leader Richard Paddock and International Trade Specialists Jay Biggs and Kimberly Shaw. Mr. Gren and Mr. Paddock interviewed government officials, industry trade associations, industry analysts, and government officials in Brasília and São Paulo, Brazil. U.S. Commercial Service (USCS) market specialists in Brazil attended these interviews and actively supported this work. Supplemental information gathered from on-site interviews and a review of available literature are also included in this report. Ms. Shaw attended the ABPVS International Regulatory Conference in Recife, Brazil, from September 3 – 5, 2003. In the body of the report, Brazilian terms are presented in English translation, accompanied occasionally by the original Portuguese words in parenthesis. A glossary of terms and abbreviations is provided for quick reference.

Finally, this report is supplemented by additional information on medical device market - in Brazil as well as other countries – that can be found on the OMMI website at: <http://www.ita.doc.gov/td/mdequip>.

TERMS & ABBREVIATIONS

\$ Unless otherwise noted, dollar figures cited in this report are U.S. dollars

ABIMED	<i>Associação Brasileira dos Importadores de Equipamentos, Produtos e Suprimentos Médico-Hospitalares</i> (Brazilian Association of Importers of Medical Equipment and Supplies)
ABIMO	<i>Associação Brasileira da Indústria de Artigos e Equipamentos Médicos, Odontológicos, Hospitalares e de Laboratórios</i> (Brazilian Association of Manufacturers of Hospital, Dental, Medical and Laboratory Equipment and Supplies)
ABRAMGE	<i>Associação Brasileira de Medicina de Grupo</i> (HMO Brazilian Association)
ANVISA	<i>Agência Nacional de Vigilância Sanitária</i> (National Health Vigilance Agency)
BNDES	<i>Banco Nacional de Desenvolvimento Econômico e Social</i> (National Economic and Social Development Bank)
CIF	cost, insurance, and freight.
CS	Commercial Service
DOC	Department of Commerce
FTAA	Free Trade Agreement of the Americas
HTS	Harmonized Tariff System
ICMS	<i>Imposto sobre Circulação de Mercadorias e Serviços</i> (Merchandise Circulation Tax)
II	<i>Imposto de Importação</i> (Import Duty)
IMI	International Market Insight
INPI	<i>Instituto Nacional de Propriedade Industrial</i> (National Industrial Property Institute)
IPI	<i>Imposto sobre Produtos Industrializados</i> (Industrial Products Tax)
IPR	intellectual property rights
ISA	industry sector analysis
MERCOSUL	<i>Mercado Comum do Sul</i> (Southern Common Market)
MDIC	<i>Ministério do Desenvolvimento da Indústria e Comércio Exterior</i> Ministry of Development, Industry and Foreign Trade

MOH	Ministry of Health (In Brazilian Portuguese, it is the <i>Ministerio de Saude</i>)
OCC	<i>Organismo de Controle e Certificação</i> Control and Certification Laboratories
OMMI	Office of Microelectronics, Medical Equipment and Instrumentation
NCM	<i>Nomenclatura Comum do Mercosul</i> (Mercosul Common Nomenclature for tariff item descriptions)
NTDB	National Trade Data Bank
REFORSUS	<i>Projeto de Reforço à Reorganização do Sistema Único de Saúde</i> (Health Sector Reform Project)
REAL	National Currency of Brazil
SECEX	<i>Secretaria de Comércio Exterior</i> Secretariat of Foreign Trade
SISCOMEX	<i>Sistema Integrado de Comércio Exterior</i> (computerized trade documentation system for import licensing)
SME	small and medium-sized enterprise
SUS	<i>Sistema Único de Saude</i> Unified Health System
USEAC	U.S. Export Assistance Center
USTR	Office of the U.S. Trade Representative
VAT	value-added tax

EXECUTIVE SUMMARY

Economic development and the increased purchasing power of the population since the early 1990s has caused demand for health services in Brazil to burgeon. Brazilian modernization and reform efforts have created a more efficient and professional healthcare system. While the country's health care system has made notable progress in recent years, the need for further improvement remains apparent, and modernization efforts still face significant challenges. Brazil's healthcare sector lags behind other Latin American countries with similar GDP per capita, despite the fact that Brazilians spent about \$40 billion on healthcare in 2002.

Perhaps the most significant initiative in recent years impacting the medical device market was the decentralization of Brazil's health care system. The government recently began re-defining rules governing state and local government health care spending, management and the institutional rights of participation in the health policy decision-making. While the federal government maintained its financing and coordination responsibilities, municipalities were given greater control of managing the local health care programs. The state governments mainly provide support for the municipal health care systems.¹

The increased emphasis on improving health care has mitigated the effects of recent economic and currency crises on Brazil's medical devices market. The market for medical devices in Brazil, including a wide array of items such as laboratory reagents and X-Ray film, was valued at \$1.1 - 1.2 billion in 2002.² Brazil presently runs a negative balance of trade in medical equipment and supplies. In 2001, imports accounted for over half the market,³ however the devaluation of the Real is likely to have a dampening effect on medical device imports. Medical device imports in 2002 were about ten percent less than the previous year, due in part to the dollar/Real exchange rate. Another major reason for the rather flat market is that the Ministry of Health has not increased its reimbursement rates for high tech procedures since 1998.

Medical equipment and supplies is a growing and dynamic sector in Brazil. Despite inherent difficulties, with patience and deliberation, many U.S. companies have had success in the market. U.S. medical device companies looking to manufacture in Brazil must obtain the necessary Federal, State and local permits, arrange for product registration with the Ministry of Health, and manufacture according to quality systems guidelines. In addition, the market essentially mandates ISO 9002 certification.

¹ Interview: Antonio Barahona, REFORSUS, Secretariat for Healthcare Investment, Ministry of Health, 5 August, 2002

² Jefferson Oliveira, U.S. Commercial Service Brazil, Industry Sector Analysis: Medical Equipment and Devices, August 2002.

³ Ibid

1. COUNTRY OVERVIEW

Brazil is South America's largest and most developed country, accounting for about one half of the economic output of South America. With a GDP exceeding \$450 billion, Brazil is the thirteenth largest economy in the world, and the fifth largest country in the world in terms of population and area. The 2002 census counted 174.5 million people (roughly half the population of South America), and the country covers 8.5 million square kilometers (roughly half South America's land mass).

Brazil - along with China and India - has increasingly become the focus of those looking to invest in emerging countries. With more than 170 million people, it is rich in agricultural, mineral and industrial resources and offers a substantial export market for U.S. exporters. In 2003, estimated U.S. exports to Brazil will reach \$10 billion, while Brazilian exports to the United States will reach \$16 billion. Most industrial economic activity is focused around the southeastern states of São Paulo, Minas Gerais and Rio de Janeiro and includes automobiles, steel, petrochemicals, computers and aircraft. Brazil's agricultural sector is well diversified, including products such as beef, orange juice, sugar cane, coffee and soybeans.

Along with the state of Bahia, the four southeastern states contain half of the population. Internal migration from the poor northeastern states continues to produce rapid urbanization in the southeast; the city of Sao Paulo alone has over 10 million residents. Crime, drug abuse, health epidemics, and environmental degradation are major problems that are exacerbated by one of the most unequal distributions of wealth in the world. Brazil's GDP per capita is listed as \$2850 for 2002, however more than 30 million live at sub-Saharan levels of poverty. Brazil's health expenditure per capita is \$240, or 5% of GDP. Yet Brazilians remain an optimistic people and are leaders in Latin America in their calls for free trade and transparent governance.

1.1 Economic Overview

The Brazilian economy experienced a period of stability in the first half of 2003, however economic uncertainty remains high and growth will be modest. Struggling in recent years, Brazil's economic condition deteriorated further in the summer of 2002 as a result of uncertainties about the fall presidential elections, its growing debt burden, and fallout from Argentina's ongoing economic crisis. Since the election and subsequent inauguration of President Luiz Inácio "Lula" da Silva in January, however, markets have stabilized somewhat and the Real has begun to rebound. Despite some lingering uncertainties, expectations for modest economic growth are reasonable; interest rates declined slightly in 2002, and GDP is forecast to grow at about 1.7% in 2003 and 3.1% in 2004, according to Latin Focus, a Barcelona-based consulting group. Continuing uncertainties about future economic plans, economic difficulties in neighboring Argentina, a sluggish world economy and government anti-inflation policies have all put a damper on economic growth in Brazil.

According to the Central Bank of Brazil, the economy actually began showing initial signs of a modest recovery between the third and fourth quarters of 2002. GDP grew 2.0% in the first quarter of 2003 and is projected at \$508 billion in 2003 (2.3% growth). This was due in part to increased consumption of semi- and non-durable goods, an increase in earnings in the agricultural sector, and the acceleration of growth in exports. Other factors credited for improved conditions included a more positive perception of the political scenario, a decline in concerns about higher unemployment and an improvement in consumer confidence. (The Consumer Intentions Index, as measured by the Federation of Commerce of Sao Paulo, increased slightly in late 2002.)⁴

Brazil ran a relatively small \$7.7 billion current account deficit in 2002 (-1.71% of GDP), mainly due to increased trade surplus and manageable interest payments on its foreign debt. According to Brazil's Central Bank, the projected deficit for 2003 is forecast to go still lower to around \$8 billion, with an expected trade surplus of \$15 billion. Financing for the current account deficit will continue to come from inflows of foreign direct investment, a trend that began with the floating of the exchange rate in 1999 and has continued over time. The Central Bank forecasts that the net inflow of foreign direct investment will be twice as large as the current account deficit in 2003. Total foreign debt dropped \$4.1 billion to US\$215 billion in the third quarter of 2002.⁵

For the foreseeable future, Brazil's economic outlook continues to look mixed. While annual inflation has held steady at around 5% for several years, it has increased in 2002 and hit a 7-year high in May at about 17%. Some analysts believe that the recent currency shocks, which have hurt imports over the past 12 B 24 months, may have a more lasting effect on inflation than originally anticipated. Despite a recent strengthening in the Real, the currency ended 2002 about 10% weaker than anticipated, and the forecast for 2003 was recently adjusted accordingly. The Brazilian Census Bureau (IBGE) reported that inflation measured by the broad national price index (IPCA) in August 2003 was 0.34%, up from July (0.2%) and June (-0.15 %). Although inflation slowed somewhat nationally toward the end of the first half of 2003, health care costs were down 0.4% in July, compared with a 0.68% rise for health care in January.

Analysts generally do not expect inflationary pressures to abate significantly through the end of the year. In fact, despite some moderation in exchange rate volatility predicted for next year, most analysts believe inflationary pressures may increase, based on the expectation that retailers are likely to pass through this year's exchange rate weakening to consumer prices.

1.2 Political Climate

Brazil is a federal republic with 26 states plus the Federal District of Brasilia. The Federal Government is comprised of the executive, legislative, and judicial branches. Brazil's Constitution was crafted in 1988, granting broad powers to the federal government. The President may be elected to two four-year terms, and appoints the cabinet. The Congress

⁴ Central Bank of Brazil; Brazilian Institute of Geography and Statistics (IBGE): December 2002

⁵ Ibid

consists of two houses, the Senate and the Chamber of Deputies. There are 81 Senators, three for each state and the Federal District, and 513 Deputies. In addition to geographic imbalance heavily weighted in favor of the less populated states, Congress is characterized by a large number of political parties. However, as a consequence of a weak party structure, senators and deputies do not always vote with their parties and party switching is commonplace. States are organized similar to the federal government, each with three branches of government. Because of mandatory revenue allocation to states and municipalities provided for in the 1988 Constitution, Brazilian governors and mayors have exercised considerable power since 1989.⁶

In 2002, all of Brazil was focused on the presidential campaign that ended with the election of four-time presidential candidate and leader of the Workers Party (PT) Luis Inácio “Lula” da Silva in October 2002. Lula defeated his challenger José Serra from incumbent President Cardoso's Brazilian Social Democratic Party (PSDB) by a comfortable majority of about 61%. The new president faces formidable political challenges. Although Lula won in a landslide, the PT is still a minority party in Congress and holds only four governorships. Despite being a minority party in the Congress, Lula and his party have reconciled diverging interests within his existing coalition, which includes those committed to orthodox economic policy and supporters of Lula's previously advocated leftist agenda. Complicating matters, the governors of Brazil's 26 states are split between the PT and the other major parties. Governors have broad powers and tend to follow their own agenda - even going against their own party when it suits them.

The election of Lula initially created concerns among international investors and capital markets, with some fearing that Brazil might default on its sizable (\$260 billion) foreign debt. Concerns were based on Lula's rhetoric during previous presidential campaigns, in which he espoused far-left positions such as ending privatization and defaulting on international debt commitments. However, during the 2002 campaign, Lula took a much more moderate and conciliatory tone in which he remained committed to Brazil's international obligations and pledged to keep spending in-line while pursuing economic growth. Once in office, Lula has defied expectations. His administration has continued, and in some cases, exceeded the economic stabilization and reform programs launched by President Cardoso. From October 2003 through June 2003, the Real recovered about 25 % of its value, easing inflationary pressures and gaining Brazil new international credibility. However, Brazil is not yet out of the woods as foreign direct investment and industrial output are both down, while new economic investment has been dampened due to high interest rates. As a result, many leading sectors – such as pharmaceuticals and manufacturing – have suffered in the last year.

Lula has staked his administration's reputation on passage of two major reforms in 2003 – the pension system and the tax code. Both require a constitutional amendment, demanding two successive votes with sixty percent approval in each chamber of Congress and years of previous attempts to achieve these reforms have failed. Tax reform faces broad political resistance, particularly from Brazil's governors and mayors

⁶ Additional information is available at www.brasilemb.org/links1.shtml.

who all have status quo interests to protect. While the tax proposal would not lower the overall tax burden, it would streamline the dozens of federal, state, and municipal taxes and do away with “cascading” taxes. The core challenge is to change the state-assessed ICMS (Merchandise and Service Circulation Tax) to a more VAT-like tax with just five, nationally standardized rates. A key obstacle is whether to collect the new ICMS at the point of production or sale. Other priorities for the Lula administration include his focus on social programs, such as the “Zero Hunger” and “Zero Illiteracy” programs.

So far, Lula’s fiscal policy appears to be a relatively smooth continuation of policies from the Cardoso administration. Meanwhile the markets will be watching Lula closely for signs of radical policy shifts or other actions that might complicate Brazil’s investment climate.

1.3 Investment Climate

Foreign direct investment (FDI) is an important source of financing for Brazil. The Brazilian Government has lifted or mitigated many restrictions over the past several years to encourage foreign investors. In 2002, Brazil attracted \$16.6 billion in foreign direct investment, down from \$22.5 billion in 2001. The recent decline in FDI reflects, in part, the slower pace of privatization in recent years, investor uncertainty in Brazil and the global decline in investment. Brazil and the United States have a balanced and expanding trade relationship with about \$30 billion in total trade annually. In 2002, one third of Brazil’s foreign investment was from the United States (\$14 billion).⁷

All foreign investment must be registered with the Central Bank within 30 days of the inflow of resources to Brazil. Registration is done electronically, and in most cases is a pro forma matter. Investors must have a representative in Brazil and be registered with the Brazilian Securities Commission (CVM). The certificate of registration permits remittances of profits and repatriation of capital without additional Central Bank authorization.

There are few restrictions on converting or transferring funds associated with an investment. At this time, foreign investors may freely convert Brazilian currency in the unified foreign exchange market wherein buy-sell rates are mainly determined by market forces. All foreign exchange transactions, including identifying data, must be reported to the Central Bank. Foreign exchange transactions on the current account have been fully liberalized in practice, and in 2000 the Central Bank greatly simplified requirements for capital account transactions.

Brazil is a signatory to the GATT Uruguay Round Accords, including the Trade Related Aspects of Intellectual Property (TRIPS) Agreement, signed in April 1994. Brazil is also a member of the World Intellectual Property Organization (WIPO) and a signatory of the Bern Convention on artistic property, the Washington Patent Cooperation Treaty, and the Paris Convention on Protection of Intellectual Property. Brazil has not yet ratified the

⁷ U.S. Department of Commerce, International Trade Administration

WIPO Treaties on Copyright and Performances and Phonograms. As a result of continuing problems regarding protection of intellectual property rights, Brazil remains on the U.S. Government's Special 301 priority watch list following the early 2003 annual review.

Although Brazil's copyright laws generally conform to world-class standards, widespread piracy of copyright and trademark material remains a problem. According to the 2003 National Trade Estimates report on trade barriers by the Office of the U.S. Trade Representative (USTR), the effectiveness of Brazil's enforcement of copyright law is limited, and lead to U.S. losses from piracy valued at \$770 million in 2002. To enhance enforcement efforts, the Brazilian Congress passed a law in July 2003 establishing prison terms of two to four years for copy right violations, including selling, renting, smuggling, hiding or acquiring counterfeit copyright and pirated products.

In the pharmaceutical sector and IPR, Brazil has a significant problem with patent backlogs. For the past three years, only a small number of the pharmaceutical patents have been processed and approved. The backlog is now over 20,000 and continues to grow every year. Part of the problem is the lack of adequate staff to process patent applications - despite the millions of dollars paid in application fees by the industry. Also, the food and drug regulatory agency (ANVISA, similar to the U.S. FDA) is also part of the patent approval process, which further slows down approvals and is not consistent with TRIPs.

Brazil has signed Bilateral Investment Treaties (BITs) with 14 countries and completed negotiations on two regional Mercosul agreements since 1994.⁸ There are two Mercosul investment-related agreements: the Buenos Aires Protocol ("extrabloc") and the Colonia Protocol ("intrabloc"); the latter has not been signed by Brazil. Seven of the bilateral investment treaties have been sent to the Brazilian Congress, but have not been ratified. The United States signed an Investment Warranty Treaty with Brazil in 1965. The United States and Brazil currently have no plans to discuss a BIT.

1.4 Trade Issues

Cooperation between the U.S. and Brazil on major trade issues runs the gamut from direct opposition to close collaboration. The U.S. and Brazil generally disagree on bilateral market access for agricultural products, and Brazil has been sharply critical of the U.S. farm bill, which it deems incongruous with the U.S. position against foreign protectionism. On the other hand, Brazil is moderately supportive of the U.S. proposal for agriculture in the WTO, acknowledging that the U.S. should not unilaterally concede certain issues without similar agreements from the E.U. and Japan.

Brazil has also led political efforts for economic integration in the Southern Cone of South America. No discussion of trade with Brazil is complete without mentioning

⁸ Mercosul (or Mercosur as it is known in Spanish) is the regional trading bloc with member nations Brazil, Argentina, Uruguay and Paraguay. Chile and Bolivia are associate members. See further explanation in Trade Issues section.

Mercosul, a treaty that established a common market among the member nations of Argentina, Brazil, Paraguay and Uruguay, including associate member nations Chile and Bolivia, facilitating the free movement of goods, services and factors of production between these countries. The agreement is designed to eliminate customs duties and non-tariff restrictions, the establishment of a common external tariff, and the adoption of common trade policies. The agreement also calls for the co-ordination of positions in regional and international economic and commercial forums, macroeconomic and sectoral policies in the areas of foreign trade and other areas. Mercosul is also meant to ensure proper competition between the States Parties and as a commitment by States Parties to harmonize their legislation in relevant areas.

Since November 2002, the United States and Brazil have co-chaired the negotiations of the Free Trade Agreement of the Americas (FTAA). Each supports common goals of the FTAA, including an open, equitable, transparent and rules-based multilateral trading system, reduced customs tariffs and increased market access. However, recent events at the Cancun WTO Ministerial meeting in September 2003 have created tensions. Brazil led the Group of 22 at the ministerial meeting, effectively collapsing the negotiations due to lack of progress on agricultural subsidies. However, the recent November 2003 meeting in Miami moved the FTAA negotiations into a new phase, setting the framework to complete the negotiations. Although the Ministers reaffirmed their commitment to a comprehensive and balanced FTAA that would most effectively foster economic growth, the reduction of poverty, development, and integration through trade liberalization, they also recognized the need for flexibility to take into account the needs and sensitivities of all FTAA partners. As such, it was declared that negotiations should allow for countries that so choose, within the FTAA, to agree to additional obligations and benefits. One possible course of action would be for these countries to conduct plurilateral negotiations within the FTAA to define the obligations in the respective individual areas. The FTAA can co-exist with bilateral and sub-regional agreements, to the extent that the rights and obligations under these agreements are not covered by or go beyond the rights and obligations of the FTAA. Both Brazil and the United States reaffirmed their commitments to successfully concluding the negotiations by January 2005.⁹ .

⁹ For further developments in the negotiations, visit the FTAA website at <http://www.ftaa-alca.org>. The FTAA Ministerial Declaration from the Eighth Ministerial Meeting, held in Miami, Florida, between November 16 – 20, 2003, is available at http://www.ftaa-alca.org/Ministerials/Miami/declaration_e.asp. The current third draft of the agreement is available at http://www.ftaa-alca.org/FTAADraft03/Index_e.asp.

2. HEALTH SERVICES IN BRAZIL

2.1 Structure of Health Care System

The Constitution of 1988, along with a series of Basic Operational Norms (*Normas Operacionais Básicas* - NOBs) enacted by the Ministry of Health (MOH), essentially defines Brazil's current public health care system and sets forth certain objectives including universality and equality of care. This led to the creation of the Unified Health System (*Sistema Único de Saúde* - SUS) in 1993, replacing the previous centralized and insurance-based model of the public health care system with a universal, free, and decentralized one. Under the SUS, all Brazilians are entitled to healthcare services within an integrated federal public, state and municipal health care network. Of Brazil's 170 million people, about 100 million rely on the SUS, while 70 million have private insurance.¹⁰

Brazil is a Federal Republic, divided into 26 states plus the Federal District of Brasilia. These are divided into 5,500 municipalities. The healthcare network in Brazil is managed and operated at federal, state, and municipal levels. The responsibilities are allocated as follows:

Federal

Ministry of Health

- National healthcare policy
- Technical co-operation with States and Municipalities
- International agreements
- Administration of SUS

State

State Secretaries of Health

- Regulate and, where appropriate, co-ordinate and assist in the delivery of healthcare services provide staff training (technical & managerial) and assist in procurement.

Municipal (local)

Municipal Secretaries of Health

- Planning, organization, delivery, control and evaluation of healthcare services.¹¹

Brazil's health care system was decentralized when the government re-defined the rules governing state and local government health care spending, management and the institutional rights of participation in the health policy decision-making. While the federal government maintained its financing and coordination responsibilities,

¹⁰ Interview: Mr. Eduardo Oliveira, President, Assocacao de Hospitais de Sao Paulo, 8 August 2002.

¹¹ Trade Partners UK: <http://www.tradepartners.gov.uk/healthcare/brazil/profile/overview.shtml> Overview of Brazil Healthcare System. 26 September 2003.

municipalities were given greater control of managing the local health care programs. The state governments mainly provide support for the municipal health care systems.¹²

In aggregate, Brazilian health care is provided by three different and somewhat independent processes: (1) the SUS, the comprehensive, publicly financed health care system involving three levels of government with free and universal entitlement; (2) a supplementary health care system, in which individuals or organizations have their own voluntary private health insurance plans; and (3) a private market of health care provision, in which people buy supplemental health care services. Generally speaking, the middle and upper classes, as well as the better-organized workers, get health care through private health insurance plans, while those lower on the socio-economic scale rely exclusively or frequently on the SUS for health care.

Health services in Brazil are provided by a mix of public and private facilities consisting of an estimated 7,000 hospitals, more than 12,000 diagnostic clinics, and about 250,000 doctors. The government out-sources a majority of inpatient care and a large part of outpatient work to private and philanthropic hospitals and clinics. In fact, the federal government manages just 30% of the hospital beds it supports, and is continuing to pass control of public facilities to states and municipalities. University hospitals continue to belong to the structure of the universities and the Ministry of Education, and the subsystem of medical care of the armed forces remains outside the SUS system.¹³

The MOH, as the coordinating body of Brazil's health policy, is divided into three Secretariats. The Secretariat of Investment is charged with distribution of funds for development. The Secretariat of Assistance to Health, which oversees 2,500 public and 3,500 non-profit hospitals, plays a significant role in defining the price of procedures. The Secretariat of Health Policies is in charge of primary care, HIV, family health and science and technology issues. The Division of Science and Technology under this Secretariat is responsible for researching new medical technologies and advising on high-end technology.¹⁴

The Municipal Health Secretariats, with the assistance of the Federal MOH authorities, are the point of delivery of public health services. They are responsible for managing their region's public health network, from the provision of primary health services to the procurement of hospital/health products. Efficiency of services differs from region to region. Now, over 90% of the Brazilian municipalities partially manage their own health network – about 10%, i.e. 560 municipalities, have complete autonomy.

It is important to note that, although the MOH is responsible for Brazil's national healthcare strategy, it is the states and municipalities who decide how to implement and deliver services in their own region. Furthermore, in recent meetings between the U.S.

¹² Interview: Antonio Barahona, REFORSUS, Secretariat for Healthcare Investment, Ministry of Health, 5 August, 2002.

¹³ Espicom Business Intelligence, MediStat Country Profile – Brazil, West Sussex, UK, October 2002.

¹⁴ Interview: Antonio Barahona, REFORSUS, Secretariat for Healthcare Investment, Ministry of Health, 5 August, 2002.

Department of Commerce (USDOC) and the Brazilian Ministry of Health, it was emphasized that the MOH is gradually transferring its control and implementation from the federal to the state and municipal levels, including the administration of funds.¹⁵ This means that local authorities should be considered the point of delivery of public health services and that they are responsible for managing its region's public health network, which ranges from the provision of primary health services to the procurement of hospital and health products. As of the fall 2003, more than 60% of the Brazilian municipalities partially managed their health services, but only 3% of them, mostly medium and large cities, had fully taken over full management.¹⁶ Brazil's huge social, demographic, and economic differences mean that planning and implementation of healthcare strategies varies considerably across the country. Also, the population's ethnic and epidemiological profile is extremely heterogeneous. Likewise, the purchase of products and services are normally carried out individually by municipalities, except in major national programs.

Health management organizations (HMOs) are becoming an increasingly important part of Brazil's health care system as politicians try to find ways to make private health care more affordable to Brazil's middle class. According to the HMO Brazilian Association (ABRAMGE), 40 million Brazilians have non-public health care assistance. This non-public service is comprised of group medicines, medical cooperatives, self-administration system and insurance companies. According to ABRAMGE, more than 48,000 companies participate in HMOs, covering more than 18 million participants and their families. The HMO provides services and access to owned and certified hospitals, as well as other medical treatments options, such as physicians, specialized treatment and preventative care programs. The medical cooperatives, or unimed, cover an additional 10 million people. The self-administration system is organized by state-owned and private companies for their employees and family members and provides assistance to nearly 8 million people. A number of leading private medical insurers maintain their own health care facilities. ABRAMGE also reports that approximately 25% of the population has no access to health assistance due to the lack of hospitals in small cities and rural areas.¹⁷

Until recently, Brazil's health care system did not allocate healthcare resources efficiently. To correct this, the MOH implemented two programs in the mid 1990's - Community Health Agents Program (Programa Agentes Comunitários de Saúde - PACS) and the Family Health Program (Programa Saúde da Família - PSF) – and made major changes in the way resources were allocated, how health care payments were made, and in the organization of services and in health-care practices at the local level. Thus, the PSF is a strategy for incremental reform of the health system. It has been strengthened in that process by the amendment of the MOH rules for the intergovernmental transfer of

¹⁵ Meeting: Brazilian Ministry of Health, in attendance Mr. Wagner Martins, General Coordinator of International Actions; Dr. Pedro Benevenuto, REFORSUS; and Dr. Antonio Claret, General Coordinator of DIPE. 13 August, 2003.

¹⁶ Ibid.

¹⁷ For further information on ABRAMGE, see their website at <http://www.abramge.com.br>.

resources, and for the form of payment of health services, by varying the procedures for transfer of resources (as defined in NOB #96).¹⁸

TABLE 2.1 - SUS OUTPATIENT FACILITIES BY TYPE

FACILITY	2002
Health Posts	12,402
Health Centers	11,805
Medical Assistance Posts	N/A
Hospital Outpatient Clinics	4,512
Maternity Clinics	N/A
First Aid Stations	492
Mixed Units	1,489
Dental Clinics	N/A
Dental Consulting Rooms	N/A
Medical Consulting Rooms	4,972
Physiotherapy & Rehabilitation Clinics	464
Psychiatric Clinics	N/A
Specialty Clinics	2,496
Diagnostic/therapeutic Centers	4,826
Mobile Units	763
Family Health Units	12,986
Other Ambulatory Facilities	4,211

Source: MediStat¹⁹

The Brazilian health care system has come to realize the need for a stronger hospital administrative system, including employing more non-physicians as administrators. As a result, a relatively recent phenomenon is the expanded role played by professional health care administrators. Until recently, many hospitals were run by families of doctors who were not well versed in modern health care administration.²⁰

2.2 Health Care Financing

Brazil's economic development and the increased purchasing power of the population since the early 1990's has caused demand for health services to burgeon, and modernization and reform have created a more efficient and professional healthcare system. Brazilians spent about \$40 billion on health care services in 2002, roughly equivalent to 8% of the GDP. The MOH invested about \$11 billion in health care modernization programs in 2002. Notably, the United States spent \$4,280 per year per

¹⁸ Interview: Antonio Barahona, REFORSUS, Secretariat for Healthcare Investment, Ministry of Health, 5 August, 2002.

¹⁹ Espicom Business Intelligence, *Medistat Country Profile: Brazil*, West Sussex, UK, October, 2002

²⁰ Interview: Mr. Eduardo Oliveria, President, Assocacao de Hospitais Estado de Sao Paulo, 8 August 2002

capita on health care in that year, while the average per capita income in Brazil is only \$3,400.²¹ According to a constitutional amendment approved in 2000, states and municipalities are obliged to spend at least 7% of their revenues on health care. They also must increase these amounts up to 12% for states and 15% for municipalities by 2005. In addition, the amendment dictates that federal health spending should increase from 2002 to 2005 accordingly to inflation and GDP variation.

Responsibility for health care issues are currently shared by the Federal Government and state and municipal health councils. Two thirds of Brazil's public health budget currently comes from the Federal budget. The public health sector in Brazil has several sources of finance: the Brazilian Treasury contributes with \$10 billion per year, whilst states and municipalities add \$3 billion. For basic health care, the municipalities receive a per capita transfer of federal money. For medium complexity procedures, municipalities currently receive a per procedure fee. This will likely change to a lump sum amount adjusted for inflation. For high complexity procedures, payment is made on a per-transaction basis.²² In 2001, the MOH contributed over \$1 billion to high complexity procedures.

Required contributions by states and municipalities were recently codified in Constitutional Amendment 29, passed in 2001. The amendment requires states and municipalities to contribute a set percentage of their budgets to public health. In 1998, the NOB was re-named the Health Assistance Operating Norms (*Normas Operacional da Assistência à Saúde* - NOAS), and given responsibility for integrating the regional management plan (*Plano Diretor de Regionalização* - PDR) and other regional health plans into an overall health strategy combining public, private, and non-profit sectors. This review process began in 2000, and currently 17 of the 27 Brazilian states have submitted plans. These plans will lead to a major overhaul in the way in which health care is funded in Brazil.

Decentralization of Brazil's medical system has given greater control over procurement and planning of local programs to states and cities. Municipalities, which in some cases partner directly with the MOH, are required to submit a health plan to a health committee overseen by the MOH describing service requirements that are specific to the population. Privatization and efficiency programs have gradually replaced the large centralized bureaucracy created during the years of military rule.

Public hospitals are dependant upon the government for their investment budget, and funding is not always consistent. As a result of this inconsistent source of funding, public hospitals put a great deal of emphasis on medical device companies' ability to provide repair services and spare parts. Some public hospitals receive a special budget from the state government for human resources (staff salaries) as well as for materials

²¹ Interview: Hospital dos Clinicas

²² Interview: Antonio Barahona, REFORSUS, Secretariat for Healthcare Investment, Ministry of Health, 5 August, 2002

(consumables, drugs, and investments). Some prestigious facilities receive the most advanced medical devices at cost so companies can claim their machines are used there.²³

The public health system must follow Public Law #8666 procedures for bidding on medical devices. These guidelines require that 2 - 3 companies must submit bids before a tendering decision is made. According to these guidelines, the selection must be made on the basis of lowest cost. Most bids take between three to six months to conduct. Some public hospitals can partially avoid following these procedures if they use money provided by a foundation. Funding for many procedures comes from the MOH, which reimburses the state Secretary of Health, which in turn sends this money to the responsible foundation. Some public hospitals can send purchase orders for various types of equipment and supplies directly to the Foundation, bypassing tendering requirements that would normally be required for a public institution.²⁴

Some private hospitals are not obligated to follow Public Law #8666 procedures for bidding on medical devices. In these cases, there are no preset time limits for the bidding process; times vary depending on the complexity of the devices being purchased. Hospitals often maintain their own list of suppliers for medical devices, medical supplies, and pharmaceuticals. Once the hospital administration submits its annual request for new equipment, a committee sends out bids to suppliers that are on its list of suppliers. Once it receives bids from three different suppliers, a committee analyses the bids. While cost reportedly plays a major part in procurement decisions (see section on market entry strategies), many private hospitals place a great deal of emphasis on the after sales service and in-country support.²⁵

In addition, the National Bank for Economic and Social Development (*Banco Nacional de Desenvolvimento Econômico e Social* – BNDES) has specific finance programs for the public healthcare sector. Brazil also has loan agreements with several multilateral organizations, e.g., World Bank and the Inter-American Development Bank. Between 2000-2002 the Brazilian Ministry of Health received US\$700 million in loans from multilateral agencies. Currently the main project financed by the World Bank is a US\$550 million program to expand and strengthen the Family Health Program (FHP), which aims to reform Brazil's public healthcare services by establishing a primary care network as the main point of entry into the public healthcare system. The loan was approved in March 2002, but its disbursement only started at the first half of 2003. Also the World Bank approved a new US\$50 million project aimed at the re-structuring the State of Bahia's healthcare system, in early June 2003. The aim of the State of Bahia project being to improve access of the poor to basic health care, to implement the national policy of health care decentralization seeking to: improve access of the poor to basic health care, as measured by 10 performance indicators that measure the coverage and quality of the health interventions with the greatest influence over child mortality, maternal mortality, and the incidence of diseases prevalent among the poor;²⁶

²³ Interview: Hospital dos Clinicas

²⁴ Interview: Mr. Joao Figureiro, Chairperson, Hospital dos Clinicas, 8 August 2002.

²⁵ Interview: Isrealita Brasileira Hospital Albert Einstein (AEH)

²⁶ World Bank: www.worldbank.com *Brazil- Bahia Health System Reform*. September 29,2003.

2.3 Challenges and Progress in Health Care

While Brazil is Latin America's largest economic engine, the healthcare sector in Brazil lags behind other Latin American countries with similar GDP per capita. Brazil's health care system has made notable progress in recent years. However, the need for further improvement remains apparent, and modernization and reform efforts in Brazil's still face significant challenges.

The uneven distribution of health care between regions of the country, caused primarily by an uneven distribution of income, remains a major issue. Some regions in Brazil have more in common with poorer countries like Guatemala and Peru. There is presently a shortage of hospital beds (Espicom Business Research estimated about 3.6 beds per thousand population)²⁷ and the system will soon be further taxed by the increasing demands of an aging population. For large segments of the population, services are often limited to basic immunization and emergency care. Theoretically, the system has the resources to meet the needs of Brazil's population, however lack of efficiency in some regions is such that many patients are forced to wait in long lines for surgery, laboratory tests and treatment.

Despite the need for further improvements, modernization and reform have produced a number of positive developments in Brazil. Overall life expectancy is increasing, infant mortality has been declining, and the increase in AIDS cases may be slowing. The government is conducting a number of targeted campaigns, including periodic vaccination programs that are free for children, woman and elders in the prescribed age range. Women's health has received a considerable amount of attention from the government and international health associations. On balance, Brazilian children are healthier; infant mortality rates and childhood height-for-age charts – two prominent indicators of the general health of children – have shown significant improvements in recent years. These improvements have been brought about by a complex interaction of improvements in purchasing power; maternal education; access to health care, including oral re-hydration therapy; community infrastructure and water supply; and individual behavior, such as increased breastfeeding and fewer short-interval births.

As noted, health and sanitary conditions in Brazil vary widely from region to region. Urban areas have a legacy of greater improvements in access to health care for children and mothers, maternal education, and reproductive practices. While the Brazilian public health care system extends to rural areas, its coverage is not extensive, and the quality and promptness of public health care is not as good as the service offered by private health care. Big cities will have many physicians who have been trained abroad, but in smaller towns and interior areas of Brazil, there is a shortage of doctors, nurses and hospitals. There are intractable regional health issues that generally correlate to the health of the economy. For example, while more than 10% of children nationwide still

²⁷ Espicom Business Intelligence, *MediStat Country Profile – Brazil, West Sussex, UK, October 2002*

suffer severe growth retardation, or "stunting", the figure rises to almost 18% in the Northeast, considered the poorest, most rural region of the country.²⁸ While facilities in certain regions are ill equipped, by and large the population in major urban cities of Brazil has access to modern diagnostic and treatment equipment and tools.

In past years, low levels of government health care funding have hampered preventative measures and programs. In recent years, however, preventive medicine is rapidly becoming an important new sector in Brazil, and increasingly resources from internal and external sources are being directed to prevention programs. For example, in 2002 the MOH began distributing funds from a \$500 million loan (\$300 million contributed by the World Bank and \$200 million from the Inter-American Development Bank) for a family health program called Health Sector Reform Project (*Projeto de Reforço à Reorganização do Sistema Único de Saúde - REFORSUS*).

REFORSUS is an innovative program designed to provide health care and extend family practitioner service to the rural poor. The program's two main goals are to decrease unneeded hospitalization (a recent MOH study indicated that 30 - 40% of medical procedures were unneeded), and to increase the availability of preventative medicine (such as teenage pregnancy and infant mortality due to dehydration). Under the program, teams of five or six health workers, generally consisting of one physician, two nurses, and two local agents trained in general medical care, are dispatched to attend to 1,000 families. Recently dentists have been added to the teams. Currently, there are 15,000 teams consisting of 75,000 professionals, and the MOH intends to increase the number to 20,000 teams. These teams need a variety of portable equipment that can be reliably used in field conditions. Funds from REFORSUS are provided to the State Health Council, which in turn controls the selection of equipment. Funds have been used to repair existing hospital infrastructure, create new units in public hospitals (such as intensive care units), and purchase medical equipment for public hospitals.²⁹

²⁸ Ibid.

²⁹ Interview: Antonio Barahona, REFORSUS, Secretariat for Healthcare Investment, Ministry of Health, 5 August, 2002.

3. BRAZILIAN MARKET FOR MEDICAL DEVICES

3.1 Domestic Medical Devices and Diagnostics Market

3.1.1 Overview

An increased emphasis on improving health care has mitigated the effects of recent economic and currency crises on Brazil's medical devices market. The market for medical devices in Brazil, including a wide array of items, such as laboratory reagents and x-ray film, was valued at \$1.1 - 1.2 billion in 2002.³⁰ Brazil presently runs a negative balance of trade in medical equipment and supplies. In 2001, imports accounted for over half the market,³¹ however the devaluation of the Real is likely to have a dampening effect on medical device imports. Medical device imports in 2002 were about 10% less than the previous year, due in part to the dollar/Real exchange rate. Another major reason for the rather flat market is that the Ministry of Health (MOH) has not increased its reimbursement rates for high tech procedures since 1998.

Main buyers of medical equipment are government, nonprofit and private hospitals, clinics and diagnostic centers. Government purchases are usually done by public bid and are restricted to companies that have a local presence. Major equipment, such as image or laboratory diagnostic equipment, is generally purchased directly from the manufacturer or its representative. Most often the local representative facilitates the importation process, but the actual transaction occurs directly between the buyer and the company outside of Brazil. There are thousands of medical device distributors throughout Brazil, mostly concentrated in the Southeast. Many distributors import, package and re-label the products in Brazil.

3.1.2 Medical Products Classification

Medical devices and supplies include everything from disposables to sophisticated electronic diagnostic and imaging equipment. Generally, Brazilian statistics lump together medical, dental and clinical laboratory equipment. In all, there are over 11,000 families of items classified as "medical equipment," which includes anything from sophisticated image diagnostic equipment to hospital furniture and special clothing. The Brazilian Association of Manufacturers of Hospital, Dental, Medical and Laboratory Equipment and Supplies (ABIMO) broadly classifies medical devices in Brazil into the following categories:

- I - Medical/hospital equipment
- II - Radiology equipment
- III - Laboratory equipment and reagents
- IV - Dental equipment
- V - Implants and consumables

³⁰ Jefferson Oliveira, U.S. Commercial Service Brazil, Industry Sector Analysis: Medical Equipment and Devices, August 2002.

³¹ Ibid.

In addition, three risk categories, roughly paralleling those established by the Food and Drug Administration (FDA) in the United States, were created:

- I - Low risk
- II - Moderate risk
- III - High risk

3.1.3 Medical Device Suppliers

Brazil's medical device market is supplied by a combination of domestic players, large multinationals with manufacturing centers in the country, and direct imports. Brazil has a number of major multinational firms that serve the Brazilian and international markets, while most are small to medium-sized companies manufacturing medical devices and low cost products for the local market. Most domestic suppliers are located in Rio de Janeiro, São Paulo and Belo Horizonte. Hospitalar, which conducts the largest medical device-related trade show in Latin America, estimates that there are around 400 Brazilian companies in the medical device sector. About 230 of these companies are mainly medical device manufacturers, while another 170 produce products that include some medical device products.³²

Brazil's domestic medical industry supplied roughly half of the market in 2001; about 80-85% of domestic production goes toward the domestic market. Brazil's medical devices industry employs about 37,000 people. In 2001, imports accounted for slightly more than half the market. Main supplies imported include diagnostic equipment and reagents, implants and prostheses. A relatively small number of Brazilian companies export. Countries purchasing medical equipment from Brazil include the United States, other Latin American countries, Africa, and the Middle East. Some Brazilian companies have broken into the western European market. Similar demographics, market conditions, and proximity, prompt many African countries to look to Brazilian medical device companies for products.³³ Important Brazilian exports include sutures (catgut and synthetics), needles, dental equipment, artificial teeth, valves, X-ray film and prosthesis. Brazil has an excellent reputation for dental equipment, and domestic dental manufacturers have exported from for many years.³⁴

Some notable Brazilian firms include Macrotec (x-ray processing equipment); Cardios (cardiac monitoring and examination equipment); JP Farmaceutica (IV fluids and IV fluid bags); Neurotec (EEG equipment); Braile (cardiac surgery support devices); NS (vaporizers, inhalation equipment); WEM (electric scalpels); Plastcalp (needles, syringes, catheters, disposable textile materials); and P. Simon (surgical drains). Notable multinationals with a local presence include GE Medical Systems, Phillips Medical, Toshiba Medical, Siemens Medical, Kodak, Shimadzu, Beckton Dickinson, Baxter, Edwards Lifesciences, Johnson and Johnson, 3M Medical, Hollister, Smith & Nephew,

³² Interview: Mauro Stormovsky, Executive Director, Hospitalar, 8 August 2002.

³³ Ibid.

³⁴ Ibid.

Guidant, St. Jude and Fresenius AG.³⁵

TABLE 3.1
MAJOR BRAZILIAN EXPORTS OF MEDICAL EQUIPMENT (2001)
(US\$ MILLIONS FOB)

Description	Value
Instruments, Syringes, etc.	44.36
Sutures, Cement, Other	28.64
Prostheses, Valves and Implants	28.55
X-Ray Film	33.43
Other Exports	29.11
Total Exports	164.11

Source: SECEX - Brazilian Government Statistics and ABIMO³⁶

Some notable examples of Brazilian medical device and supplies exporters by category include:

- *Anesthesia* - Brazilian companies Takaoka, Intermed and J.G. Moriya manufacture quality anesthesia machines. Takaoka is the market leader in both volume and quality, exporting to other countries in Latin America, Africa and the Middle East.
- *Incubators* - Fanem, a Brazilian company specializing in industrial heating equipment, also manufactures top line incubators exported throughout the world. Gigante Recém Nascido is another Brazilian company recently established to compete with Fanem in this line.
- *Surgical Instruments* - Edlo, Erwin Guth, Schobell Industrial, Lido and Richter are considered top line Brazilian manufacturers of surgical instrumentation.
- *Implants and Prostheses* - Brazilian companies Baumer, Biomecanica and Ortosintese produce artificial joints and other implants that are exported to Latin America.

3.1.4 Imports of Medical Equipment and Supplies

About half (in value) of all medical equipment is still imported in Brazil. This includes high unit value products such as imaging systems, as well as catheters, pacemakers, diagnostic reagents, and other high volume, lower priced items. The main importers of medical equipment are large non-profit hospitals, government hospitals and companies importing equipment for re-sale. Brazil is considered a good base for medical device

³⁵ Jefferson Oliviera, U.S. Commercial Service Brazil, *Industry Sector Analysis – Medical Equipment and Devices*, August 2002

³⁶ Brazilian Medical Device Industry Association (ABIMO)

companies looking to access the growing Latin American market. When asked about problems associated with importing medical devices and supplies, Brazilian officials point to fluctuating exchange rate and the need for better financing packages.³⁷

TABLE 3.2
SUMMARY OF IMPORTS BY EQUIPMENT (2000)

	<i>Total (\$K)</i>	<i>% Total</i>
Electromedical Equipment	115,857	19.2
Medical X-ray, Alpha Beta, Gamma Ray Apparatus	101,297	16.8
Orthopedic & Prosthetic Appliances	90,177	15.0
Other Medical & Surgical Instruments	86,039	14.3
Syringe, Needles & Catheters	58,971	9.8
Medical Supplies	54,194	9.0
Medical X-ray Film	42,011	7.0
Therapy Apparatus	12,092	2.0
Ophthalmic Instruments & Appliances	10,605	1.8
Other	31,913	5.3
TOTAL	603,156	100.0

Source: MediStat³⁸

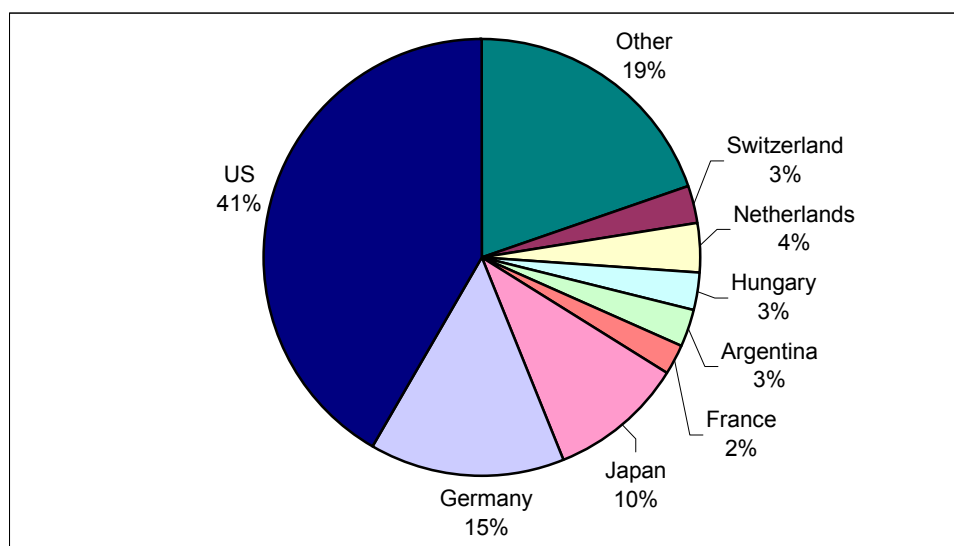
The United States is the leading foreign supplier of medical devices to Brazil, with about 40% of the import market in 2000. Other foreign suppliers include Germany and Japan, with about one quarter of the import market. Among importers, the U.S. is the leading source for medical dressings, sutures, surgical and some dental goods, medical and surgical sterilizers, syringes and other needles, catheters and cannulae and ophthalmic instruments and appliances; orthopedic and prosthetic appliances; medical, surgical and dental furniture; and some X-ray equipment including X-ray tubes.³⁹

³⁷ Interview: Mauro Stormovsky, Executive Director, Hospitalar, 8 August, 2002.

³⁸ Espicom Business Intelligence, *MediStat Country Profile: Brazil*, West Sussex, UK, October, 2002.

³⁹ Oliviera, Jefferson, U.S. Commercial Service Brazil, Industry Sector Analysis- Medical Equipment and Devices, August 2002.

GRAPH 3.1
BRAZIL IMPORTS BY COUNTRY- 2000 (%)



Source: Medistat⁴⁰

TABLE 3.3
U.S. DOMESTIC EXPORTS OF MEDICAL EQUIPMENT TO BRAZIL
(In 1,000 Dollars)

List Of Commodities	1999	2000	2001	2002	Percent Change 2001 – 2002
334510 Electromedical Equipment	127,090	132,339	140,881	124,377	-11.7%
334517 Irradiation (X-Ray) Apparatus	51,798	70,061	80,448	62,814	-21.9%
339112 Surgical & Medical Instruments	62,736	71,720	78,835	65,439	-17.0%
339113 Surgical & Medical Supplies	30,169	33,258	33,703	36,184	7.4%
339114 Dental	8,253	10,890	16,574	11,568	-30.2%
Total	280,046	318,267	350,441	300,384	-14.3%

Sources: Statistics have been compiled from tariff and trade data from the U.S. Department of Commerce, the U.S. Department of Treasury, and the U.S. International Trade Commission.

⁴⁰ Espicom Business Intelligence, *MediStat Country Profile: Brazil*, West Sussex, UK, October, 2002

A number of hospital associations are beginning to develop e-commerce sites for purchasing medical devices. The Brazilian Hospital Federation (BHF), which represents 4,500 hospitals, 93% of which are private, introduced in April 2001 an e-commerce site (<http://www.fbh.com.br>) in which member hospitals list the pharmaceuticals and medical devices and supplies they are looking to procure. Currently, 400 of the BHF's members are actively participating in this website. Recently, BHF has allowed sellers to list specifications and pictures of their equipment. While the initial listing is free, BHF intends to charge a fee of three percent of the sale price for sales made via this e-commerce system.⁴¹ Similarly, the Associação de Hospitais do Estado de São Paulo is also planning to develop an e-commerce system for its hospitals that will allow them to consider a wider variety of suppliers to whom they currently have access.⁴²

3.2 Market Opportunities and Best Sales Prospects

3.2.1 Image Diagnostic Equipment

The market for image diagnostic equipment, one of the largest in terms of value, has significant potential for American companies looking to export to Brazil. Once limited to only the most upscale facilities, sophisticated diagnostic tools are now widely available in all major urban centers in Brazil. Public and private hospitals, as well as diagnostic centers, import this type of equipment. As the market for the instruments themselves matures, companies are focusing more and more on systems integration within the medical facility, i.e. providing connectivity across all diagnostic systems.

GE Medical Systems and Phillips are the market leaders in Brazil, jointly holding over 70% of the import market. Also in the market are Siemens, Kodak, Toshiba, Shimadzu and others. The Brazilian market for imaging diagnostic equipment approached \$200 million in 1999. The market fell sharply in 2000, primarily as a result of the economic uncertainty and sharp decline in the currency expected early in the year.⁴³

TABLE 3.4
BRAZILIAN MARKET FOR VARIOUS TYPE OF IMAGING EQUIPMENT (US\$
(\$Million 2000))

Equipment	Value	Percent of Total
Tomography	33	20
Magnetic Resonance	37	24
X-Ray	33	20
Nuclear	8	5
Ultrasound	50	31

Source: GE Medical Systems

⁴¹ Interview: Ms. Carmen Bruder, Brazilian Hospital Federation (BHF), 6 August 2002.

⁴² Interview: Mr. Eduardo Oliveira, Associação de Hospitais do Estado de Sao Paulo 8 August 2002.

⁴³ Oliviera, Jefferson, U.S. Commercial Service Brazil, Industry Sector Analysis – Medical Equipment and Devices, August 2002.

Notable commodities exported by U.S. firms in 2002 included HTS 9022.14 (apparatus based on the use of x-rays for medical, surgical, or veterinary use) valued at \$12.7 million, an increase of 35% over 2001; HTS 9022.19 (apparatus based on the use of x-rays for other use, except medical, surgical, dental or veterinary) valued at \$2.2 million, an increase of 35% over 2001; HTS 9022.21 (apparatus based on the use of alpha, beta, or gamma radiations) valued at \$2.3 million, an increase of 14% over 2001; and HTS 9022.30 (x-ray tubes) valued at \$6.2 million, an increase of 41% over 2001.

3.2.2 Endoscopy

The Brazilian endoscopy market is the largest in South America, valued at about \$47.8 million in 2000, and as the economy returns to normal growth, the endoscopy market is expected to expand. Analysts project that growth should average between 6-8% per year through 2004, with flexible scope instrumentation showing the largest growth at 15.5% per year over this period. Karl Storz (Germany) is the market leader in Brazil with about 37% of the market share for new products, followed closely by Smith & Nephew (Great Britain) with about 20% of the market. Olympus (U.S.) and Wilson Cook (U.S.) are the third and fourth largest market competitors, with market shares of 16.8% and 10.3%, respectively.⁴⁴

3.2.3 Cardiology Equipment

According to the Brazilian Medical Device Industry Association (ABIMO), sales of certain categories of medical devices increased notable in 2001-02. One such category was cardiology equipment including cardiology implants and disposables and pacemakers.⁴⁵ The market for cardiology devices and supplies is an important one in Brazil, and a number of products, including pacemakers and echocardiography equipment, are imported. While there is some locally manufactured electrocardiogram equipment, it is generally of lesser quality. Most pacemakers are imported; some 10 to 12 thousand are installed each year. Pacemakers are price-controlled by the government, and as of May 2002 was \$1,400.

The United States is the leading supplier of pacemakers and a leading supplier of electrocardiographs. In 2002, U.S. exports to Brazil of pacemakers (HTS 9021.50 for stimulating heart muscles, excluding parts and accessories) were valued at more than \$8.1 million, an increase of 32% over the previous year.⁴⁶

3.2.4 Dialysis Equipment

Brazil is the fourth largest potential market in the world for dialysis equipment, with a dialysis population that is growing at a rate of 12% per year. U.S. company Baxter and German company Fresenius not only supply dialysis machines, but have also been

⁴⁴ Ibid.

⁴⁵ Interview: Mr. Ronaldo Pitta, Brazilian Medical Device Industry Association (ABIMO), 7 August 2002.

⁴⁶ Jefferson Olivieira, U.S. Commercial Service Industry Sector Analysis: Medical Equipment and Devices, 21 August 2002.

aggressively purchasing dialysis centers. As a result, Baxter and Fresenius currently dominate the market. Two Brazilian companies B Sistemas Vitais and Assis Med B also manufacture dialyses. No coils are manufactured locally, although some 50-55 thousand coils are used in Brazil every month, most of them polysulphone, which cost about \$15-20 each.⁴⁷

In 2002, the United States exported more than \$14 million of dialysis instruments and apparatus (HTS 9018.90.7020) to Brazil. The decline from \$19 million in 2001 can be attributed mainly to a decline in economic conditions. Parts and accessories for dialysis instruments and apparatus (HTS 9018.90.7070) were valued at \$3.2 million for 2002.⁴⁸

3.2.5 Disposable materials

The disposable materials market is one of the fastest growing markets in Brazil's health care sector - the overall market is expected to grow 11 B 13% for the next 5 years. The total market size for disposable materials is estimated at over \$1 billion. The largest volume in this segment is made up of disposable syringes and needles B some 1.2 billion units are sold each year. The United States is the main supplier of certain disposable medical materials including products like needles, syringes, catheters, cannulas, etc. Beckton Dickinson (BCD) dominates the market as the only manufacturer able to meet government demand in times of vaccination campaigns. U.S. exports of hypodermic syringes (HTS 9018.31.0040), with or without needles, increased by 185% in 2002. BCD has been present in Brazil for many years and operates two manufacturing facilities - one in Curitiba and one in Juiz de Fora. Other suppliers include Injex, Plascalp, SR and Ibra.

Other important disposable medical equipment include catheters, with an estimated total market of \$250 million (mostly imported), and vacuum tubes for blood collection (vacutainers), with consumption of 450 million units per year. The local manufacturing of vacutainers started in 2001; gynecology/proctology disposables are a market of some \$2-4 million.⁴⁹ Growth in this segment is expected to come from oral dosing syringes, vacutainers and catheters. The market for syringes is considered mature, as new pharmaceuticals tend to be for oral administration.⁵⁰

While exports of some categories of disposables declined, largely due to economic conditions, some categories were notable in size or had dramatic increases. In 2002 the United States exported more than \$2.7 million worth of adhesive dressings and other articles having an adhesive layer, roughly equivalent to exports in 1991. U.S. exports of items in the HTS 3006.10 category (sterile surgical catgut, sterile suture materials and surgical wound closures, and similar sterile surgical materials) increased by more than 100% to more than \$2.8 million.

⁴⁷ Ibid.

⁴⁸ U.S. Department of Commerce Export Statistics

⁴⁹ Kollplast.

⁵⁰ Oliveira, Jefferson, U.S. Commercial Service, Industry Sector Analysis, Medical Equipment and Devices Brazil, August 2002.

3.2.6 Diagnostic reagents

The laboratory equipment and reagent market is also growing with the major hospitals having large labs and many private labs running tests and full clinics. Multinational companies have the largest part of market share in diagnostic reagents. Among them, the most important are Abbott Labs, Roche, Bayer, Millipore, Kodak and Beckman-Coulter.

3.2.7 Other

The medical device market sectors that have the best growth potential include any device that can replace an existing device at a lower cost than servicing the older device. Brazil is a good market for SMEs for products that are near the end of their product life cycle, and no longer in demand in some of the more advanced markets. Selling in Brazil allows SMEs to extend the life of an existing product line (those that are less than the state of the art) while using the sales income to re-invest in more advanced products.⁵¹

Other key market sectors include emergency care (including sterilization equipment emergency rooms), cancer related diagnostics, point of care treatment, and telemedicine. Devices and supplies for dentistry are also a growing market segment. Dentistry has a great deal of room for growth; there are only 150,000 dentists in Brazil, and only about 10% of the population (70 million people) have access to quality dental care.⁵² Various categories of U.S. exports in dental equipment and supplies that increased last year included HTS 9021.29 (dental fittings and parts and accessories) valued at \$1.4 million and HTS 9021.21.4000 (artificial teeth of plastic plus parts/accessories).⁵³

3.2.8 Used and Refurbished Medical Equipment

In February 2003, Brazil's healthcare monitoring agency, ANVISA, implemented new legislation affecting imports of all healthcare products that included an outright ban on the import of used (not reconditioned) products.⁵⁴ Currently, Brazil allows refurbished equipment only if the equipment is donated, and only for hospitals that are expanding their supply of equipment (i.e. not replacing existing medical equipment).⁵⁵

Brazil approved a law that regulates the import of refurbished medical equipment. Companies that are interested in this niche have to comply with a rigid set of guidelines, including, date of refurbishment, accurate adjustment & calibration. The refurbished equipment must meet the exact same performance of new equipment. Also, the manufacturer must provide technical assistance in Brazil or designate a local representative to provide the service.

⁵¹ Interview: Mr. Jose Manuel Iaranjeiras, President, ABIMED, 6 August 2002.

⁵² Interview: Mauro Stormovsky, Executive Director, Hospitalar, 8 August 2002.

⁵³ U.S. Department of Commerce Statistics

⁵⁴ PJB Publications, Clinica, Issue 1050, 21 March 2003.

⁵⁵ Interview: Ronaldo Pitta, Brazilian Medical Device Industry Association (ABIMO), 8 August 2002.

On February 15, 2003, the Brazilian National Health Vigilance Agency (ANVISA) published resolution RDC n° 25, which regulates imports of used medical equipment. The resolution imposes strict requirements that used equipment must meet before it can be imported into the country. Some of the requirements include:

- Registration with Brazil's *Vigilância Sanitária* agency, ANVISA. If the product does not require such registration, submit evidence to support your claim;
- Obtain an import license. The license must state the country of origin, detailed information of product, name of manufacturer, model and technical specifications;
- The equipment must be thoroughly cleaned and refurbished;
- All parts and pieces subject to wear and tear must be replaced;
- The equipment must be professionally calibrated to meet original specifications which must be certified by the original manufacturer;
- New labels must be affixed and an instruction manual must be provided;
- Submit the year the equipment was refurbished;
- The equipment must pass thorough quality control tests; and
- Make spare parts and components available in Brazil during the useful life of the equipment.

There are severe penalties for companies that do not follow the requirements listed above, including assessment of stiff fines and even confiscation of the equipment. Therefore, it is critical that U.S. exporters of used medical equipment coordinate closely the transaction with the Brazilian importer. The Department of Commerce strongly advises U.S. companies to obtain the services of a reputable Brazilian customs brokerage firm with significant experience related to imports of medical equipment.⁵⁶

3.3 Market Entry Strategies

New-to-market exporters should of course learn as much as possible about the Brazilian economic and commercial environment before doing business there. It is especially important for potential direct exporters to familiarize themselves with local business practices specific to Brazil. For example, negotiations are often slower than in the United States, and usually require personal contact; rarely are important business deals conducted by telephone or letter. Conversely, continuity is important; quick and infrequent visits by foreign sales representatives are not viewed favorably. Brazilian buyers also place a premium on after-sales service and support, and marketers should be well prepared to discuss technical issues in depth.

It is especially important that correspondence and product literature be in Portuguese, and English is preferred as a substitute over Spanish. It is important that companies use proper Brazilian Portuguese translations (not Spanish or European Portuguese) of all

⁵⁶ Global Import Regulations for Pre-Owned (Used and Refurbished) Medical Devices, Steven Harper, U.S. Department of Commerce – ITA/OMMI, September 4, 2002. Available at <http://www.export.gov/mdequip>.

documents, including translations of instructions written on the medical device itself. Although translations of all manuals and other documents are required to register a product, non-Brazilian firms often neglect to do this for instructions or warnings on the equipment. This can be a problem, as many of the support staff using equipment cannot read English. Specifications and other technical data should be in the metric system.

The three most common ways of entering the Brazilian market are: 1) hire an agent, 2) hire a distributor, and 3) form a Brazilian company to import your equipment. Should you choose to hire a distributor or agent, it is important to find a company that knows the medical device market and has good contacts. It is also important to identify a distributor familiar with Brazil's regulatory system and has good relations with Brazilian regulatory authorities.⁵⁷ You also need to make sure that the firm you hire has the capacity – including staff, time and resources - to adequately represent your product. A good approach is to look for executives who have recently retired from medical device companies in Brazil. Often these people will be willing to represent one or more medical device importers, and have the contacts to do so effectively. In addition, if you choose to hire a distributor it is important to make sure that you include a clause in the contract explicitly state that the registration for your medical device is transferable to another distributor at your discretion, because under Brazilian law, registration belongs to the local representative.

Officials interviewed for this report generally agreed that the key to selling in the Brazilian market is cost effectiveness. If your products are not significantly less expensive than your competitors, then this market may not be appropriate.⁵⁸ According to Hospitalar, around 60 - 65% of sales in the Brazilian health care market are based mainly on price, 15% based on quality and the remaining 20 - 25% of sales are based on other non-economic factors like after sales service.⁵⁹

The Brazilian medical supplies market is much more price-sensitive today than in the past. A number of companies from lesser-developed countries (e.g. China, Pakistan, India) are competing with U.S. companies on the basis of price, especially in the lower end of the market and increasingly in more technologically sophisticated medical devices niches. Often the willingness of these companies to transfer technology, in addition to their low price structure, makes them formidable competitors in the Brazilian market.

Price structures should have flexibility. Due to the weak Real, many medical device importers have to give a 10 - 20% commercial discount to hospitals (especially public hospitals) in order to compete in the Brazilian market. However, market analysts advocate that importers keep their list prices (which is what the MOH uses in its reimbursement calculations) as high as the market permits, thus allowing an importer to offer commercial discounts. Another suggested approach to keep prices low is to ship medical devices partially assembled, then have an affiliate complete assembly in Brazil.

⁵⁷ Interview: Ronaldo Pitta, Brazilian Medical Device Industry Association (ABIMO), 8 August 2002.

⁵⁸ Interview: Mr. Jose Manuel Iaranjeiras, President, ABIMED, 6 August 2002.

⁵⁹ Interview: Mauro Stormovsky, Executive Director, Hospitalar, 8 August 2002.

This not only reduces the import duties that you pay, but will also make your product “made in Brazil” for purposes of exporting to other Mercosul countries.

Potential exporters should be aware of the life cycle of medical device products in Brazil. In a typical scenario, a small or medium-sized company with a unique product will begin marketing in Brazil through distributors at low volumes and high prices. In time, larger companies will notice the profit margins and begin operations in Brazil. The ensuing price competition will reduce profit margins, prompting some or all of the major companies to pull out of the market, but continue to do a limited amount of business through a distributor. For example, in 2001 Brazil imported 24,000 stents, mainly through distributors who bought the stents at about \$460 per stent, then sold them in Brazil for around \$4,000. By the middle of 2002, a number of large medical device companies had entered the Brazilian market directly, selling 3.7 million stents (projected sales total for 2002). However, the end-price for stents had fallen to \$166 per stent.⁶⁰

U.S. medical device companies looking to manufacture in Brazil must obtain the necessary federal, state and local permits, arrange for product registration with the MOH, and manufacture according to quality systems guidelines. In addition, the market mandates ISO 9002 certification.

3.4 Notable Influences on the Market

There are a number of growing influences on the healthcare sector, and therefore the medical device market, worthy of note:

1. **Increased Competition:** In June 1998, new legislation concerning the private health assistance market was enacted. The main consequences of this new law were: a) the market was opened to foreign companies; b) all companies have to be inspected and regulated by Brazilian insurance authorities (in the past only health insurance companies were formally audited and inspected by the Government); and c) all companies will have to comply with minimum capital requirements and offer a minimum package of services. The legislation is still going through adjustments, as a result of pressures from the companies and customers.
2. **Women=s Health:** The market for products associated with women’s health is growing as evidenced by the increasing number of mammograms and pap smears each year. The public health system conducts some 1 million mammograms and 8 million pap smears each year, double the number five years ago. The total market for mammography equipment is not available, but this service is available across the country. Thanks to a concerted government campaign, infant mortality has declined in recent years – from an estimated 50 deaths per thousand live births in 1990, to about 30 deaths per thousand live births in 2000.

⁶⁰ Interview: Mr. Jose Manuel Iaranjeiras, President, ABIMED, 6 August 2002.

3. **Trend Towards Home Care:** Home healthcare is also a major growth area. Health insurers realize the lower costs involved in healthcare at home versus nursing homes and hospitals. There are over 180 companies specializing in the sector. 2001 revenues were some \$100 million, and insurance companies cover most of the costs. Surveys indicate that there are over 11,000 patients under home care treatment in Brazil.

4. **Telemedicine and Medical Applications of Information Technology (IT):** While difficult to quantify, the application of IT in healthcare is a growing and dynamic sector in Brazil. Most major hospitals use some form of telemedicine, including video links with hospitals in the United States or Europe, whereby patient records and images can be transmitted for opinion and consultation. Companies that manufacture image diagnostic equipment are also actively pushing systems integration solutions as a means to secure “captive” clients. Systems integration is a growing market in Brazil, and the major players are Siemens, Toshiba, Phillips and GE Medical Systems.

5. **Preventative Medicine:** Degenerative, infectious and parasitic diseases, including AIDS, cancer, tuberculosis, malaria, and dengue fever, are common disorders amongst the very poor, most notably in the North. The spread of HIV and AIDS in the 1990s was rapid; Brazil presently has the third highest rate of AIDS in the world. In many instances, the spread of this disease can be traced to Brazil's poorly regulated blood supply.⁶¹

6. **Managed Care:** Brazilian health care companies are under increasing pressure to modernize and improve their services due to increasing competition, which will follow from the operation of foreign companies in Brazil in this sector. Managed care is one of the tools that the Brazilian private health assistance plans are considering to improve efficiency. In addition, private health assistance companies, like the public health sector, are now investing heavily in preventive programs aimed at reducing their claim's rate in the short and longer term.⁶²

⁶¹ Interview: Mauro Stormovsky, Executive Director, Hospitalar, 8 August 2002.

⁶² Oliviera, Jefferson, U.S. Commercial Service, Industry Sector Analysis – Medical Equipment and Devices, August 2002.

4. REGULATION OF MEDICAL DEVICES

4.1 Overview

In Brazil, the MOH controls all health-related products. Regulations are strictly enforced. Some products may be exempt from registration, but this can only be determined by the MOH. Medical devices are regulated by Brazilian Law #6.360/76, decree 74.094/97. In January 1996, the Secretariat for Sanitary Inspection (SVS) published a joint decree (Portaria Conjunta n1 1, January 23, 1996) setting forth the requirements for registration in Brazil. This decree is no longer in force, but was replaced by Resolução #185, dated October 22, 2001.⁶³ As stated in the resolution (Annex, Part 3.5.d), the manufacturer or importer must provide a certificate of free sale, certificate from foreign government (CFG) or other equivalent documents, granted from the appropriate and competent government authority where the medical device is manufactured and/or commercialized. The new regulation does require submission of clinical trial data for new technologies or therapies.

Although the process is codified, rules governing the registration of medical products in Brazil are not always clear or applied consistently, and the process can be long and laborious. Brazilians recognize their system is not easy and are beginning to discuss the need for changes. A recent regulatory professional conference highlighted the need for a better and less laborious regulatory system, while balancing the constitutionally granted right of access to basic healthcare and protecting the citizenry. The Brazilian National Health Vigilance Agency's (ANVISA) product registration requirements are not always fully updated, as they are dependent on Mercosul for the newest requirements.⁶⁴ ANVISA is also moving towards making as many of its databases and information publicly available online.⁶⁵ The following information, considered current as of the publication of this report, is meant for general guidance. Prudent exporters should investigate the process thoroughly with agents and distributors and, if possible, other exporters with current registration experience. A recent roundtable meeting in Brazil with U.S. companies and Brazilian importers highlighted the importance of U.S. exporters making technical information submissions understandable, as sometimes government reviews may not have the complete and necessary technical expertise.

The Ministry of Health (MOH) oversees regulations governing the importation of medical device in Brazil. However, ANVISA, an agency similar to the U.S. Food and Drug Administration (FDA) created specifically to help monitor medical devices and other items (e.g. pharmaceuticals, cosmetics and foods), conducts most regulatory duties. ANVISA conducts product registration, provides operating licenses, and issues import and export approvals.⁶⁶ All medical devices must be registered with ANVISA in order to

⁶³ A full copy of Resolution #185, dated 22 October, 2003, is available at http://www.anvisa.gov.br/legis/resol/2001/185_01rdc.htm.

⁶⁴ ABPVS International Regulatory Professional Conference, Recife, Brazil. 3 – 5 September 2003.

⁶⁵ ANVISA's website is <http://www.anvisa.gov.br>. While it is in Portuguese, ANVISA has also translated some of its information into English and Spanish.

⁶⁶ Interview, Mr. Paulino Araki, President National Agency of Sanitary Health (ANVISA), 5 August 2002.

be sold in Brazil. At a recent ABPVS conference, it was noted that ANVISA does not have enough inspectors to complete all required product inspections. ANVISA is able to handle inspections of high risk medical products, but businesses may find themselves waiting a long time for inspections of low risk medical products.⁶⁷ Another comment made at the conference was ANVISA's need to begin focusing on post-registration surveillance of products for efficacy and safety. A new decree, n° 385, dated June 4, 2003, is aimed at focusing on post-registration surveillance of medical products.⁶⁸

Companies that wish to export to Brazil must have an office or local distributor registered with the MOH as an importer and distributor of the type of products being offered. Product registrations must be requested through the company's subsidiary or agent in Brazil. Products are normally registered in the distributor's name, and if companies wish to switch distributors, re-registration is often required. The registration is valid for 5 years. The registration process must be completed within 90 days from the date the registration request is initiated, however the process (including the cost of certification) can cost a company as much as \$40-50 thousand, and may take between six months to a year.⁶⁹ The MOH in Brazil accepts international approval certificates issued in other countries, e.g., FDA and CE Mark.

Under the Brazilian Law of Similar, a medical device imported into Brazil may not have to pay duties, provided there is no similar product manufactured in Brazil and the medical device is being sold to a hospital. However, the foreign companies or local importers must apply for this exemption. First, ANVISA gives the foreign company or importer a one-year temporary product registration for the duty exemption. Once a hospital sends in its request to purchase the medical device and includes the proper documentation (catalogues and brochures must in Portuguese), then the Secretariat of Foreign Trade (*Secretaria de Comércio Exterior* - SECEX), an arm of the Ministry of Development, Industry and Foreign Trade (*Ministério do Desenvolvimento da Indústria e Comércio Exterior* - MDIC), begins its analysis of the product. Finally, SECEX contacts the Brazilian Association of the Industry of Medical, Dental, Hospital and Laboratory Articles and Equipment (*Associação Brasileira da Indústria e Artigos e Equipamentos Médicos, Odontológicos, Hospitalares e de Laboratórios* – ABIMO) to find out if there are any similar products locally manufactured by Brazilian firms. In approximately 80% of the medical device cases, there are no similar products. If ABIMO says that there are similar Brazilian made products, a company has the opportunity to appeal this decision in the Brazilian court system. According to ABIMO, this has only been done once or twice, and the process takes roughly two years (during which time a company can simply pay the duties and import the equipment into Brazil).⁷⁰

⁶⁷ ABPVS International Regulatory Professional Conference, Recife, Brazil. 3 – 5 September 2003.

⁶⁸ Ibid.

⁶⁹ Interview: Mr. Jose Manuel Iaranjeiras, President, ABIMED, 8 August 2002

⁷⁰ A recent roundtable meeting in Brazil with Brazilian importers reiterated this point that the Law of Similar is applied sparingly by Brazilian authorities. (Roundtable with U.S. Companies and Importers, held in São Paulo, Brazil, on 12 August 2003.)

There have been a number of changes in Brazil's regulatory environment in 2003. For example, in the past, if a company wanted to make minor changes to a product, it would have to re-register the product. Now companies can make minor changes (e.g. an increase in the size of a monitor) and still use the same registration number. In addition, there has been a trend toward classifying new companies as the "registration keeper" that holds the product rights on behalf of the foreign company. These local companies can designate and replace the importer or distributor according to the exporter needs, avoiding changes in the product registration at the MOH.

4.2 Import Licenses

Only licensed importers can import products into Brazil. Licenses to import are issued by SECEX. The Brazilian import process operates through a computerized system called the Foreign Trade Integrated System (*Sistema de Comércio Exterior* or SISCOMEX). The SISCOMEX process begins with the submission by a manufacturer of a pro-forma invoice ("*fatura proforma*") and a published list of prices or sales catalog from the supplier (if such exists). The original copy should be notarized, but need not be accompanied by a Chamber of Commerce certification or consular visa. The pro-forma invoice must contain the following information:

- Name and address of the manufacturer or exporter;
- A signed statement by the exporter or manufacturer verifying that the prices are current export market prices for destination to any country;
- If applicable, the name and address of the agent, distributor, representative, or concessionaire in Brazil, and a statement of commission due. [Note: this is not necessary when the agent has filed a general statement with SECEX of fees collected from a particular foreign firm.] If no representative exists, this must be so stated;
- Total FOB price, unit price, gross and net weight, itemized freight and all other expenses, and total CIF value; and,
- If applicable, a statement declaring that published catalogs or price lists do not exist for the invoiced products.

After submission of the pro-forma invoice, the manufacturer will be notified that before an import license can be issued, the medical device must be registered with ANVISA.

U.S. manufacturers wishing to sell their products in Brazil must either register their products through a Brazilian subsidiary or a local agent or distributor - only companies with a presence in Brazil can apply for product registration. The Brazilian representative or distributor must contact the MOH and file with the intent of registering and licensing the product(s) it wishes to import. When the request has been approved, the equipment must then be registered with ANVISA. Registration of brand names and patented technology with the Brazilian National Industry Property Institute (INPI) is also recommended.

4.2.1 Protective Measures

Medical device exporters to Brazil should consider certain protective measures in order to assure their rights during registration. To protect the manufacturer's rights, exporters should craft a solid contract with their distributor that includes references to the ownership of its registration with the MOH. Specific clauses in the contract should be established, transferring the ownership of the registration from the agent to the manufacturer, thus minimizing risks. Transfer to another agent is extremely difficult to obtain, and can only occur if the foreign company opens an office or plant in Brazil, since no registration can be transferred overseas. Manufacturers should be aware they must disclose to local authorities, through their agents, the quantitative and qualitative formula of their products, which should be patented in Brazil, before the product is introduced into the market, and at the time of registration. This has to be described on the registration document.

Before signing a contract with a distributor, companies should check the distributor's references and find out who their other clients are. It is also advisable to check with the MOH to make sure that the distributor is registered to handle your particular type of product. There have been instances in which a distributor is licensed to distribute another type of medical device, but is required to apply to MOH for a license for your particular product. This process includes audits of storage and selling facilities, and can take up to a year, during which they cannot sell your product. Also, a company should check to see which Brazilian states the distributor is licensed to sell in. If a distributor is licensed to distribute a product in one state, they can usually transfer their license to other states in Brazil. Finally, for quality control certificates, a company should contract with a local certified Brazilian laboratory for product to be registered. Laboratories must be an "*Organismo de Controle e Certificação,*" (Control and Certification Laboratories or OCC) an officially certified organization, registered with the Brazilian Ministry of Health. The company has 12 months to provide this information. The company can use any laboratory authorized by the MOH.

The Association of Brazilian Regulatory Affairs Professionals (*Associação Brasileira Profissional em Vigilância Sanitária - ABPVS*) is a source of information for rules governing registration. According to ABPVS, there have been a number of changes over the past few years making it much easier to import medical devices into the Brazilian market. Perhaps the biggest change came as a result of recent legislation that allows companies to register a family of similar products, instead of having to register each product separately. In October 2001, Brazil amended its regulations governing the certification of resale to accept the certification of medical devices from countries other than the country in which the company is registered. This means that a U.S. company that manufactures medical devices in Europe, and has the CE mark on its product, will have the CE mark accepted by Brazilian authorities.⁷¹

⁷¹ Interview, Ms. Eliana Silva Moraes, Association of Brazilian Regulatory Affairs Professionals (ABPVS), 7 August 2002.

The Brazilian MOH also allows third parties to test medical devices. According to officials from the *União Certificadora* (UC), a non-profit third party testing institute, importers can register their products without certification, if, due to its technical sophistication, no Brazilian lab can test the medical device.⁷² In this case a company can go directly to the ANVISA office and ask for product registration without having certification or the accompanying audit. Brazilian customs will not allow importation without this registration number. Certification bodies, such as UC, will often write a letter to ANVISA stating that they are unable to perform certification tests on a particular device.⁷³ There is also a growing realization among Brazilian medical device regulatory professionals of the pressing need for international harmonization of regulations. Some medical products are exempt from registration, including some parts and accessories of medical products and non-sterile products used exclusively for support of medical or laboratory procedures.

4.3 Registration Requirements

In order for products to be accepted by Brazilian customs, it is a legal requirement for the products to have directions for use in Portuguese and to have Portuguese product labels. Labels must include product name and intended use; manufacturing and sterilization date; methods of sterilization; expiration date; MOH product registration number; name and registration number of responsible technical person at the Brazilian distributor's office; and, manufacturer's and distributor's names (the distributor holding the registration) and appropriate addresses.

Some medical products are exempt from product registration, including:

- Non-sterile products used as exclusive support for medical procedures
- Non-sterile products used as exclusive support for laboratory procedures
- Products for physical education, beauty or aesthetic
- Parts or accessories of non-sterile and noninvasive products used as exclusive for medical procedures
- Parts or accessories of medical products exempt of registration

The following is the list of documents required for MOH registration:

- Certificate of Free Sale or Certificate to Foreign Government⁷⁴
- Letter of Authorization (for Distributors)
- Performance Specifications
- Finished Product Drawing
- List of Materials
- Manufacturing Flow Chart
- Labels

⁷² Ibid

⁷³ Interview, Mr. Paulino Araki, President National Agency of Sanitary Health (ANVISA), 5 August 2002.

⁷⁴ Certificates of Free Sale or Certificates to Foreign Governments are available from the U.S. Food & Drug Administration (FDA). Please visit their website at <http://www.fda.gov> or contact the Trade Information Center at 1-800-USA-TRAD(E) for more information.

- Directions for Use
- Indications
- Precautions, warnings, contra-indications
- Sterilization Parameters
- Sterility Test Reports
- Design Verification Tests (Quality Control Tests)
- Biocompatibility data and
- Clinical data

While registration requires FDA approval (i.e. Certificate of Free Sale or Certificate to Foreign Government), FDA approval alone will not suffice. ANVISA takes the position that since the FDA does not permit imports into the United States based exclusively on ANVISA's certification, it will not approve FDA certification as the sole requirement.⁷⁵

Registration also requires:

- Proof of payment of the registration fee (currently \$10,000 Reais).
- Copy of the operating permits for the manufacturing site, issued by the State Health Secretariat and by the Federal Secretariat for Sanitary Inspection (SVS).
- Copy of the certificate of technical responsibility.
- Two copies of the instructions for use and patient information and label model (and electronic file).
- Technical report as described in the appendix of the joint decree (Portaria Conjunta n°1, January 23, 1996) and documents showing product safety, detailed (exploded view) of the equipment inner parts and user manual.
- Proof of registration with the appropriate regulatory body in the country of origin. For products that do not require such registration, a certificate of free trade as described in appendix VII of the joint decree (Portaria Conjunta n°1, January 23, 1996).
- A copy of a power of attorney authorizing the petitioner to represent and sell the product in Brazil. This document must be in Portuguese or be a certified translation into Portuguese in the case of imported equipment.

Additional documents required for Mercosul registration include:

- Letter of authorization
- Packaging materials
- Quality control certificate
- Biocompatibility reports
- FDA approval

⁷⁵ Interview: Mr. Jose Laranjeira, President, Brazilian Association of Importers of Medical Equipment and Supplies (ABIMED), 12 August 2003.

The following chart shows the additional documentation required for medical device registration by the Brazilian government as compared to several other Latin American nations.

Table 3.6
Specific Documents Necessary for Product Registration

Requirement	Brazil	Argentina	Peru	Colombia	Venezuela	Uruguay
Certificate of free sale or certificate to foreign government	X	X	X	X	X	X
Letter of authorization (for distributor)	X	X	X	X	X	
Performance specification	X	X	X			
Finished product drawing	X	X		X	X	
List of materials	X	X		X	X	
Manufacturing flow chart	X			X	X	
Labels	X	X	X	X	X	
Directions for use	X			X	X	
Sterilization parameters	X	X		X		X
Finished product quality control test methods/representative test report	X	X	X	X	X	
Clinical publications	X				X	
Product brochure	X		X	X	X	X

Source: Medical DeviceLink-Brazil, <http://www.devicelink.com/mddi/archive/00/07/005.html>, October 3, 2003.

ABIMO states that 20 - 30% of products in the Brazilian market are not registered, a problem it is working to resolve by asking ANVISA to conduct audits of private and non-profit hospital. Public hospitals utilize public bidding procedures that require registered products.⁷⁶ At the recent ABPVS conference, held in September 2003, ANVISA stated it was looking at closing a loophole in the regulations that permitted products to be sold even if only a part of the product, and not the entire product, had been registered.

4.3.1 Product Exemptions

To lower the cost of medical device imports, the Brazilian government reduced the import duties and value-added taxes (VAT) on forty-two medical device products to 0%. The product group types are listed below:

- Isotopes and radioactive compounds
- Catgut, surgical sutures and similar products
- Blood typing reagents
- Preparations for radiological examination

⁷⁶ Interview: Ronaldo Pitta, Brazilian Medical Device Industry Association (ABIMO), 7 August 2002.

- Cement and similar preparations for dental filling
- X-ray films and similar goods
- Other X-ray films
- Culture media for microorganisms development
- Diagnostic reagents for laboratory testing
- Plastic Tubes for special applications
- Plastic washers for utilization in urology equipment
- Surgical gloves
- Syringes
- Instruments and apparatus for blood transfusion, kidney treatment, endoscopes and related products
- Prostheses
- Orthopedic products
- Other prostheses products (heart valves, intraocular lenses)
- Other - automatic defibrillators

4.3.2 Standards

Brazil usually accepts U.S. product standards and certifications by U.S. testing laboratories, such as Underwriters Laboratory (UL), as well as the CE Mark standard.

4.3.3 Labeling

Product labels must contain information about the product's quality, quantity, composition, price, guarantee, shelf life, origin, and risks to the consumer's health and safety. Labels should have a Portuguese translation and should use metric units or show a metric equivalent.

4.3.4 Costs

While ANVISA gets some money directly from the MOH, it prefers to limit its reliance on MOH funding and, therefore, gets most of its operating budget from fees. One of the issues that U.S. companies face is the substantial cost of certification by ANVISA. In order to avoid these high costs, instead of exporting their product separately, some U.S. equipment manufacturers opt to have their product included as a part of a whole device that is exported to Brazil. Another common practice is to ship unfinished products for final assembly in Brazil. Finally, now that Brazil allows foreign firms to repatriate their profits, many U.S. firms are manufacturing in Brazil. Doing so allows firms to take advantage of the (slightly) cheaper labor rates, and makes it easier to participate in bids from Brazilian medical institutions.

Nevertheless, the costs of importing products into Brazil are significant. Duties and tariffs are Brazil's primary form of regulating their trade deficit, and are subject to

arbitrary change. All tariffs are ad valorem, levied on the cost plus insurance plus freight (CIF) value of the import.

Import duties (*Impostos sobre Importação – II*) for medical equipment vary from 0% to 20%. For further counseling on Brazil’s duties and tariffs, contact the U.S. Department of Commerce’s Trade Information Center (TIC) at 1-800-USA-TRAD(E) (1-800-872-8723) or visit their website at <http://www.export.gov/tic>. It is also recommended you contact Brazilian customs for the most update information and guidance on Brazilian import duties and customs.

The Industrial Products Tax (*Imposto Sobre Produtos Industrializados - IPI*) applies to both imported and locally manufactured products, and is about 10% depending on the product category. The IPI is a federal tax levied on most domestic and imported manufactured products. It is assessed at the point of sale by the manufacturer or processor, in the case of domestically produced goods, and at the point of customs clearance in the case of imports. The tax rate varies by product and is based on the product's CIF value plus duties; it normally ranges from 0% to 20%. In general, a relatively low tariff rate carries a lower IPI tax rate and a relatively high tariff rate carries a correspondingly higher IPI rate.

The Merchandise Circulation Tax (*Imposto Sobre Circulação de Mercadorias e Serviços - ICMS*) is the local state value-added tax (VAT) and varies among the states between 12% and 18% - the rate in São Paulo is 18%. The ICMS tax on imports is assessed ad valorem on the CIF value, plus duties, plus IPI. The ICMS is based on taxes collected on sales, minus those paid in purchasing raw materials and intermediate goods. Although importers have to pay the ICMS to clear the imported product through Customs, it is not necessarily a cost item for the importer, because the amount paid represents a credit to the importer. When the product is sold to the end-user, the importer debits the ICMS, which is included in the final price of the product and is paid by the end-user.

Effectively, the ICMS tax is paid only on the added value, since the cost of the tax is generally passed on to the buyer in the price charged for the merchandise. The ICMS tax due to the state government is based on taxes collected on sales by the company, minus the taxes paid in purchasing raw materials and intermediate goods. The ICMS tax is levied on both intrastate and interstate transactions and is assessed on every transfer or movement of merchandise.

Hypothetical Calculation of Brazilian Tariffs & Taxes

-The hypothetical cost buildup for an imported machine, shipped in a 20-foot container, from the port of Miami to the port of Santos, is calculated in the following example. The free-on-board (FOB) price of the product is US\$100,000.

FOB Price of Product	\$100,000
Estimated Freight	\$2,400
Insurance (0.5% - 2%)	\$1,000
Total CIF Price	\$103,400

Landing Charges:	
II (Import Duty) (19% of CIF)	\$19,646
IPI (Industrial Products Tax) 5% of CIF + Import Duty	\$6,152
ICMS (Merchandise Circulation Tax/VAT) 12% - 18% on CIF + Import Duty + IPI)	\$23,256
Total Landing Costs	\$49,054
Port Costs	
AFRMM (Merchant Marine Tax) 25% of Ocean Freight <i>**Does not apply to Air Freight</i>	\$600
Warehouse Tax (for a 15-day waiting period) 0.65% of CIF or minimum US\$170 to maximum of US\$245)	\$235
Terminal Handling Charges Average US\$100 per container	\$100
Compulsory contribution to Custom Broker's Union 2.2% CIF or minimum of US\$71 to maximum of US\$160)	\$160
Customs Brokerage Fee (average) 0.65% CIF or minimum of US\$170 to maximum of US\$450	\$450
Computerized Foreign Trade Integrated System (SISCOMEX) usage fee	\$30
Cargo Transportation Company fee	\$35
Bank Costs 1% to 3% of FOB	\$2,000
Total Port Costs	\$3,619
CIF Price of Product	\$103,400
Landing Charges	\$49,054
Port Costs	\$3,610
FINAL Costs	\$156,064

Source: "Industry Sector Analysis - Medical Devices", U.S. Department of Commerce, U.S. Commercial Service, August 2002.

Customs clearance in Brazil can be a time consuming and frustrating process, similar to other countries in the region. In a report issued by ICEX (Instituto de Estudos das Operações de Comércio Exterior), the average customs clearance time in Brazil was the slowest in the Hemisphere (150 hours). Products can get "caught up" in customs because of minor errors or omissions in paperwork.

4.3.4.1 Advance Rulings on Classification

If there is doubt about the Harmonized System (HS) classification for your product, a request for advance ruling may be presented to the Internal Revenue Department (*Secretaria da Receita Federal - SRF*) of the Ministry of Finance (*Ministerio da Fazenda - MF*), preferably through a Brazilian representative. Samples and specifications should be included with the application. A ruling in response to such requests may take months.

4.3.4.2 Import Taxes Exemption

Non-profit organizations are exempt from import taxes and the ICMS for imported products that do not have a “similar” domestically-manufactured product. As mentioned previously in Section 4.1, ABIMO is the organization responsible for evaluating the existence of a locally manufactured similar product. They are lobbying for the same conditions for domestic products, given that these are subject to ICMS tax regardless of whether or not they are sold to a non-profit organization.

5. ROLE OF U.S. DEPT. OF COMMERCE

5.1 International Trade Administration

The mission of the U.S. Department of Commerce's International Trade Administration (ITA) is "to create economic opportunity for U.S. workers and firms by promoting international trade, opening foreign markets, ensuring compliance with trade laws and agreements, and supporting U.S. commercial interests at home and abroad. Trade Development (TD) and the U.S. Commercial Service (USCS) divisions of ITA are responsible for export promotion. ITA's Market Access and Compliance unit assists U.S. businesses that have country specific market access problems for their products and monitors foreign countries' compliance in trade agreements. For more information on ITA, visit <http://www.trade.gov>.

EXPORT.GOV Website

For more information on how the U.S. Government assists U.S. businesses export, visit <http://www.export.gov>. Export.gov is a multi-agency trade portal that brings together U.S. Government export-related information under one easy-to-use web site, organized according to the intended needs of exporters, especially small businesses. Whether a company is exploring the possibility of exporting, searching for trade partners, seeking information on new markets, or dealing with trade problems, this web site can help. Additionally, the site has easy links to information on advocacy, trade events, trade statistics, tariffs and taxes, market research, export documentation, financing export transactions, and much more.

Participating Export.gov agencies include:

- Department of Commerce
- U.S. International Trade Administration (ITA)
- U.S. Commercial Service
- Trade & Development Agency
- Department of Energy
- Export-Import Bank
- Foreign Agricultural Service / USDA
- Department of State
- Agency for International Development
- Overseas Private Investment Corporation
- Small Business Administration
- Department of Transportation
- Department of the Treasury
- United States Trade Representative

5.2 Trade Development

ITA's Trade Development (TD) unit is the Commerce Department's link to U.S. industry. TD provides industry and market analysis, export promotion services, advocacy for U.S.

companies bidding on foreign government contracts, and support for trade negotiations. TD offers an array of services to help small businesses increase their export potential.

Industry Expertise

TD's industry expertise encompasses the majority of U.S. business sectors. Industry sector specialists provide U.S. firms with: information and analysis of domestic and foreign industry trends; foreign market conditions and opportunities for specific products or services; information on foreign market tariffs and non-tariff barriers and regulations; advocacy assistance; business and cultural practices; and advice on business and cultural practices.

Trade Negotiations and Agreements

TD's industry expertise is the primary source used in trade negotiations by the President of the United States and the Office of the U.S. Trade Representative (USTR). TD's close interaction with industry, understanding of restrictions on market access, product standards and testing requirements, and knowledge of trade data assist negotiators in the drafting of trade agreements with maximum benefits for U.S. firms. Additionally, TD industry experts help monitor and enforce foreign governments' compliance with trade commitments through collaboration with other ITA units, including the USCS and Market Access and Compliance (MAC) regional desk officers, as well as USTR.

TD's Information Technologies Industries Sector

TD's Deputy Assistant Secretary for Information Technology Industries (ITI) oversees the activities of three offices focused on high-tech industry: the Office of Information Technologies and Electronic Commerce (OITEC); the Office of Microelectronics, Medical Equipment, and Instrumentation (OMMI); and the Office of Telecommunications Technologies (OTT).

Office of Microelectronics, Medical Equipment & Instrumentation (OMMI)

OMMI covers electronic components such as electron tubes, printed circuit boards, semiconductors, capacitors, resistors, transformers, and connectors, as well as semiconductor manufacturing equipment. Additionally, the office supports several industry sectors with high IT content, including medical and dental equipment and electro medical apparatus, process control instruments, laboratory analytical instruments, optical instruments, and instruments used to measure electricity and electrical signals.

OMMI Medical Equipment team's mission is to support the growth and competitiveness of the U.S. medical equipment industries in foreign markets.

OMMI's primary mission is to promote exports and increase the international competitiveness of U.S. industry. It counsels U.S. firms on foreign market conditions and the specifics of exporting, using information from overseas USCS offices and a wide range of industry-related resources. OMMI staff work with private sector and

Department of Commerce colleagues to develop trade missions, trade fairs, catalog shows, seminars, and other trade events that offer direct contact with foreign government officials, industry representatives, and end-users. In cooperation with other parts of ITA and U.S. government agencies, the office participates in trade negotiations and supports USTR efforts to eliminate or reduce regulatory and other types of barriers that hinder trade and investment in these industries.

OMMI conducts market research and statistical analysis of the domestic and international medical equipment industry and posts a variety of industry information to the <http://www.export.gov/mdequip> web site. OMMI also contributes the medical equipment chapters featured in the Department of Commerce *U.S. Industry & Trade Outlook* publication.

To obtain more information, including OMMI international trade specialists and the regions/industry sectors they cover, contact:

Office of Microelectronics, Medical Equipment & Instrumentation (OMMI)
U.S. Department of Commerce, Room 1015A
14th Street & Constitution Avenue, N.W.
Washington, DC 20230
Phone: 202-482-2470
Fax: 202-482-0975
Website: <http://www.export.gov/mdequip>

5.2.1 Other Trade Development Offices and Programs

Trade Information Center

TD's Trade Information Center (TIC) is an excellent first stop for new-to-export companies seeking export assistance from the federal government. TIC Trade Specialists: 1) advise exporters on how to find and use government programs; 2) guide businesses through the export process; 3) provide country and regional business counseling, foreign import tariff/tax rates and customs procedures, trade opportunities and best prospects for U.S. companies, distribution channels, standards, and common commercial difficulties; 4) provide information on domestic and overseas trade events; and 5) provide sources of public and private sector export financing.

TIC trade specialists also assist exporters in accessing reports and statistics from the computerized National Trade Data Bank and direct them to state and local trade organizations that provide export assistance.

To contact the TIC, call 1-800-USA-TRAD(E) (1-800-872-8723) or 202-482-0543, fax 202-482-4473; e-mail: TIC@ita.doc.gov; or visit the Web site <http://www.export.gov/tic>.

Advocacy Center

The Advocacy Center (AC) aims to ensure that U.S. companies of all sizes are treated fairly and evaluated on the technical and commercial merits of their proposals for foreign government tenders. Advocacy assistance is wide and varied, but often involves U.S. companies that must deal with foreign governments or government-owned corporations. Assistance can include the visit of a high-ranking U.S. government official to a key foreign official; direct support by U.S. officials (including Commerce and State Department officers) stationed overseas at the U.S. Embassies and Consulates; or, coordinated action by U.S. government agencies to provide maximum assistance. The AC is at the core of the President's National Export Strategy and its goal is to ensure opportunities for American companies. Since its creation in 1993, the AC has helped hundreds of U.S. companies in various industry sectors win foreign government contracts valued at more than \$2.5 billion. For more information, visit the AC's Web site: <http://www.export.gov/advocacy>.

Trade Missions And Trade Events

Working in coordination with the private sector the US&FCS, and TD industry analysts help plan, organize, and execute trade events, including high-level executive missions with the Secretary or Under Secretary of Commerce. Additionally, there are a host of trade conferences and shows held throughout the U.S. and abroad. A searchable list of all ITA trade events can be found at <http://www.usatrade.gov>.

Small Business Program

ITA's Small Business Program is the focal point for trade policy issues concerning SMEs. The program brings the small business point of view to international trade policy discussions, primarily through the Industry Sector Advisory Committees (ISAC) on Small and Minority Business for Trade Policy Matters (ISAC 14), the only advisory committee to the U.S. Government on small and minority business export concerns. The Small Business Program also provides outreach to and plans events for small, women-owned, and minority-owned firms.

Additional information can be found on the Industry Consultations Program's Web site at <http://www.export.gov/icp>, or by contacting the:

Industry Consultations Program
U.S. Department of Commerce
Tel: 202-482-3268
FAX: 202-482-4452
E-mail: Trade_Advisory_Center@ita.doc.gov

Industry Consultations Program

Industry has a voice in U.S. trade policy formulation through the Industry Consultations Program (ICP). The ICP includes more than 500 members and is comprised of seventeen

(17) Industry Sector Advisory Committees (ISACs) on Trade Policy Matters and three (3) Industry Functional Committees (IFACs) on Trade Policy Matters. The ISACs represent industry sectors of the U.S. economy, including IT and small and minority businesses. The IFACs address crosscutting issues affecting all industry sectors - customs, standards, intellectual property rights, and e-commerce. Advisors on these committees have direct access to trade policymakers at the Department of Commerce and the USTR and help develop their industry's positions on U.S. trade policy and negotiation objectives.

Additional information can be found on the ICP's web site at <http://www.export.gov/icp>, or by contacting the:

Industry Consultations Program (ICP)
U.S. Department of Commerce
Tel: 202-482-3268
FAX: 202-482-4452
E-mail: Trade_Advisory_Center@ita.doc.gov

Export Trading Companies and Trade Intermediaries

The Office of Export Trading Company Affairs (OETCA) promotes the formation and use of export trade intermediaries and the development of long-term joint export ventures by U.S. firms. OETCA administers two programs available to all U.S. exporters. The Export Trade Certificate of Review Program provides antitrust protection to U.S. firms for collaborative export activities. The MyExports.com™ program is designed to help U.S. producers find export partners and locate export companies, freight forwarders, and other service firms that can facilitate export business. For more information, visit <http://www.export.gov/oetca> and <http://www.myexports.com>.

Market Development Cooperator Program

MDCP is a competitive matching grants program that builds public-private partnerships by providing federal assistance to nonprofit export multipliers such as states, trade associations, chambers of commerce, world trade centers, and small business development centers. These multipliers are particularly effective in reaching and assisting small- and medium-sized enterprises (SMEs). Applicants use their own creativity to design projects that will help SMEs to enter, expand, or maintain market share in targeted overseas markets. MDCP awards help underwrite the start-up costs of exciting new export marketing ventures which these groups are often reluctant to undertake without federal government support. For more information, visit <http://www.export.gov/mdcp>.

5.3 U.S. Commercial Service

The USCS, one of TD's sister units in ITA, assists U.S. firms in realizing their export potential by providing: 1) exporting advice; 2) information on overseas markets; 3) assistance in identifying international trading partners; 4) support for trade events; and 5) advocacy, among other services. USCS trade specialists work in more than 100 Export

Assistance Centers across the United States and in more than 150 overseas posts, in approximately 80 foreign countries, which combined represent more than 96 percent of the world market for exports. Lists of trade specialists by U.S. city or country can be found at <http://www.usatrade.gov>.

International Operations

Overseas USCS offices are housed in U.S. Embassies and Consulates where Commercial Officers serve as intermediaries to foreign markets. USCS staff members are industry-focused and offer numerous products and services that assist U.S. companies to enter or expand their sales in a particular market. The main activities of these offices include establishing key industry and foreign government contacts, helping match U.S. suppliers with local buyers, and organizing or facilitating trade events. Contact information for USCS trade specialists who cover the IT, telecommunications, and e-commerce sectors in Brazil is listed in the appendices of this report. The website of the USCS in Brazil is: <http://www.FocusBrazil.org.br>.

Domestic Operations

The USCS provides export counseling and marketing assistance to the U.S. business community through its 1,800 trade experts working in more than 100 domestic Export Assistance Centers (USEACs) located across the country. USEAC staff work closely with their USCS colleagues stationed overseas to match U.S. suppliers with foreign buyers. USEACs help firms enter new markets and increase market share by identifying the best markets for their products and services, and developing an effective market entry strategy informed by input generated in the overseas offices. They also advise clients on practical exporting matters such as distribution channels, programs and services, and relevant trade shows and missions, as well as assisting with trade finance programs available through federal, state, and local entities.

For the nearest USEAC to your business, contact the Trade Information Center (TIC) at 1-800-USA-TRAD(E) (1-800-872-8723) or visit the *Export.gov* portal at <http://www.export.gov> and click on “Export Assistance Center”.

5.3.1 USCS Services

The USCS provides many services to assist U.S. businesses in the following areas of market research, export opportunities and export promotion. Please note that USCS Services are fee-based – for the cost of each service, you can contact the Trade Information Center (TIC) at 1-800-USA-TRAD(E) (1-800-872-8723) or your nearest U.S. Export Assistance Center (USEAC).

Market Research

Industry Sector Analysis (ISA)

ISAs are structured market research reports produced on location in leading overseas markets and cover market size and outlook, with competitive and end-user analysis for the selected industry sector. ISAs are available through the U.S. Commercial Service's Web site <http://www.export.gov> and are a component of the National Trade Data Bank (NTDB) subscription service detailed below.

International Marketing Insight (IMI)

IMIs are written by overseas and multilateral development bank staff and cover information on the dynamics of a particular industry sector in one foreign market. IMIs are available through the U.S. Commercial Service's Web site <http://www.export.gov> and are a component of the NTDB subscription service detailed below.

Country Commercial Guide (CCG)

CCGs are prepared annually by U.S. Embassy staff and contain information on the business and economic situation of foreign countries and the political climate as it affects U.S. business. Each CCG contains the same chapters, covering topics such as marketing U.S. products, foreign trade regulations and standards, investment climate, business travel, and in-country contact information. CCGs are available at <http://www.export.gov> under "Market Research."

National Trade Data Bank (NTDB)

The U.S. Commercial Service contributes to the NTDB, a one-stop source of international documents, including market research reports, trade leads and contacts, statistical trade data collected by federal agencies that contains more than 200,000 trade-related information, and Country Commercial Guides. The NTDB subscription may be purchased on CD-ROM, accessed through the Internet (<http://www.stat-usa.gov>), or is accessible free of charge at federal depository libraries. Call 1-800-STAT-USA for more information and ordering instructions.

Export Opportunities

Platinum Key Service

The Platinum Key offers customized, long-term assistance to U.S. companies seeking to enter a new market, win a contract, lower a trade barrier, or resolve complex issues. Fees depend on the scope of work.

Gold Key Service

The Gold Key is a custom-tailored service for U.S. firms planning to visit a country. This service provides assistance in developing a sound market strategy, orientation briefings, introductions to pre-screened potential partners, interpreters for meetings, and effective follow-up planning. The fees range from \$150 to \$700 (for the first day) per country.

Flexible Market Research (FMR)

FMR provides customized responses to questions and issues related to a client's product or service. Available on a quick turnaround basis, the research addresses overall marketability of the product, key competitors, and price of comparable products, customary distribution and promotion practices, trade barriers, potential business partners, and more. Fees vary according to scope of work.

International Partner Search (IPS)

IPS provides a customized search that helps identify well-matched agents, distributors, licensees and strategic alliance partners. A fee of \$600 per country is charged.

BUYUSA.COM

BuyUSA.com (<http://www.buyusa.com>) is a unique partnership between the U.S. Commercial Service and the Global Trade and Technology Network (GTN). It established a one-stop international marketplace for U.S. small to medium-sized enterprises to identify potential international partners and transact business on-line. The BuyUSA.com e-marketplace includes managed/targeted trade leads, on-line catalogs, automated searching and sourcing, financing, logistics, currency conversion, due diligence, landed-cost calculation, and tariff and duty calculation. BuyUSA.com is the only Web site of its kind to combine an on-line interface with a worldwide network of one-on-one trade counselors.

Export Promotion

International Buyer Program (IBP)

IBP, supporting 28 major domestic trade exhibitions annually, undertakes for each show a worldwide promotional campaign aimed at maximizing international attendance through work with the overseas network of Commercial Service and Embassy offices. Qualified buyers and prospective distributors, many brought as part of delegations led by overseas commercial staff, are assisted in meeting with interested exhibiting firms and provided services aimed at helping them find new suppliers and trade partners. Each show features an International Business Center at which export counseling, matchmaking, interpreter and other business services are provided to international visitors and exhibitors.

Video Conferencing Programs

The "Virtual Matchmaker," "Video Gold Key," and "Video Market Briefing" programs provide an effective tool to help U.S. companies assess an overseas market or overseas business contacts before venturing abroad to close a deal. Companies can use these cost-effective video services to interview international contacts, get a briefing from overseas industry specialists on prospects and opportunities, or develop a customized solution to international business needs.

Matchmaker Trade Delegations

The Matchmaker Trade Delegation Program is designed to match small to medium-sized new-to-market or new-to-export U.S. firms with qualified business contacts abroad. Each mission targets major markets in two or three countries that have strong potential for U.S. goods and services. Delegation members travel to each country and benefit from export counseling, interpreter service and logistics support, market research, in-depth market briefings, and a personalized itinerary of business appointments screened by commercial specialists at U.S. Embassies and Consulates.

Product Literature Centers

This program showcases U.S. company product literature through exhibits in international trade shows held in both mature and emerging markets. The Product Literature Center is a low cost, efficient way for small and medium-sized firms to get worldwide sales leads in their particular industry. A Commerce Department industry/international specialist or the U.S. Embassy operates Product Literature Centers. Visitors to Product Literature Centers are required to register and may take company literature with them. All sales leads are sent directly to the Product Literature Center participant.

Multi-State Catalog Exhibitions Program

This program showcases U.S. company product literature in fast-growing markets within a geographic region. The U.S. Department of Commerce and representatives from state development agencies present product literature to hundreds of interested business prospects abroad and send the trade leads directly to U.S. participants.

Commercial News USA (CNUSA)

CNUSA, a catalog-magazine containing advertisements of U.S. products, is published 12 times per year by the Commercial Service through its private-sector partner, ABP International, to promote U.S. products and services to more than 400,000 potential buyers and partners in 145 countries.

5.4 Market Access & Compliance

ITA's Market Access & Compliance (MAC) unit assists U.S. businesses by lowering trade barriers, including easing of market restrictions and monitoring foreign governments' compliance in trade agreements. MAC's top priority is "Keeping foreign markets open to American businesses and workers" and "looks for exporting problems caused by foreign governments and uses every possible tool to achieve equal treatment for U.S. companies and workers."

Market Access

U.S. exporters sometimes encounter trade barriers. For instance, a country may only allow products to enter the most inconvenient port or a country may treat imported goods differently than domestic goods. MAC receives calls from businesses, associations and international U.S. commercial offices, and we then map out a plan to solve the problem.

Compliance

The United States is a party in over 250 trade agreements. But trade agreements are only paper unless foreign governments comply with their obligations. MAC addresses compliance problems quickly and aggressively. Once a problem is identified, MAC organizes a team to outline and implement a solution.

MAC is divided into the Trade Compliance Center (TCC) and offices staffed with country desk officers. For further information, including regional offices and country desk officer information, visit the MAC webpage at <http://www.mac.doc.gov>.

Trade Compliance Center

The [Trade Compliance Center](#) (TCC) in the [U.S. Department of Commerce's International Trade Administration](#), is the U.S. Government's focal point for monitoring foreign compliance with trade agreements to see that U.S. firms and workers get the maximum benefits from these agreements. The TCC is the one-stop shop for getting U.S. government assistance in resolving the [trade barriers or unfair situations](#) you encounter in foreign markets.

For additional information about the TCC:

Trade Compliance Center
Market Access and Compliance/ITA
U.S. Department of Commerce
14th Street and Constitution Avenue, NW
Washington, D.C. 20230
Phone: 202-482-1191
Fax: 202-482-6097
E-Mail: tcc@ita.doc.gov
Website: <http://www.tcc.mac.doc.gov>

Appendix I Contact Information

Additional information on business customs in Brazil is available from the U.S. Embassy and Consulates in Brazil.

For complete visa and customs requirements for Brazil, travelers may contact the Brazilian Embassy at 3009 Whitehaven St. N.W., Washington, D.C., 20008; telephone (202) 238-2818, e-mail: consular@brasilemb.org; website: <http://www.brasilemb.org>. Travelers may also contact the Brazilian consulates in Boston, Houston, Miami, New York, Chicago, Los Angeles, or San Francisco. Addresses, phone numbers, web and e-mail addresses, and jurisdictions of these Consulates may be found at the Brazilian Embassy website above.

For complete information on travel to Brazil, including safety and security, crime, traffic and road conditions, and medical and health information, business travelers may wish to consult the Department of State consular information sheet, located on Consular Affairs web site at www.travel.state.gov.

U.S. Government Agency Contact Information

Office of Microelectronics, Medical Equipment & Instrumentation
U.S. Department of Commerce - ITA
Room 1015A
Washington, DC 20230
Phone: 202-482-2470
Fax: 202-482-0975
Website: <http://www.export.gov/mdequip>

U.S. Commercial Service – Brasilia
Street Address: SES – Av. das Nações, Quadra 801, Lote 03
Brasilia – DF
70403-900
Mailing Address: Foreign Commercial Service
Brasilia – Unit 3500
APO AA 34030-3500
Phone: 55-61-312-7418
Fax: 55-61-312-7656
E-mail: brasilia.office.box@mail.doc.gov
Website: <http://www.focusbrazil.org.br>

Jefferson Olivieria
Commercial Specialist – Healthcare Industries & Services
U.S. Commercial Service – São Paulo
Street Address: Rua Estados Unidos, 1812
Jardim Paulista

01427-002 São Paulo, SP
Mailing Address: Amcongen São Paulo
Unit 3502
APO AA 34030
Phone: 55-11-3897-4038
Fax: 55-11-3062-6924
E-mail: Jefferson.Oliveira@mail.doc.gov
Website: <http://www.focusbrazil.org.br>

Trade Information Center (TIC)
U.S. Department of Commerce
1300 Constitution Avenue, NW
Suite M-800
Washington, DC 20230
Phone: 1-800-USA-TRAD(E) (1-800-872-8723)
(Monday – Friday, 8:30am – 5:30pm EST)
Fax: 202-482-4473
Website: <http://www.export.gov/tic>
Email: TIC@ita.doc.gov

Brazilian Government Agencies

Ministry of Health
Ministerio da Saude
Esplanada dos Ministerios - Bloco G, 5o. Andar
70058-900 Brasilia, DF
Phone: 55-61-315-2425
Fax: 55-61-224-8747
Website: <http://www.ms.gov.br>

National Health Vigilance Agency (ANVISA)
Agencia Nacional de Vigilancia Sanitaria
Esplanada dos Ministerios
Bloco G, 9o. andar, Sala 956
70058-900 Brasilia DF
Phone: 55-61-226-9169
Fax: 55-61-315-2269
Website: <http://www.anvisa.gov.br>

Ministry of Industry, Commerce and Tourism (MICT)
Ministerio da Industria, do Comercio e do Turismo
Esplanada dos Ministérios, Bloco J, 6 floor
70096-900 Brasília, DF
Phone: 55-61-225-8105
Website: <http://www.mict.gov.br>

Secretariat of Foreign Trade (SECEX-MICT)
Secretaria de Comercio Exterior
Esplanada dos Ministerios
Bloco J, 8 floor, Sala 812
70056-900 Brasilia, DF
Phone: 55-61-329-7085
Fax: 55-61-329-7075
Website: <http://www.mict.gov.br>

Ministry of Finance (Tariff Queries)
Ministerio da Fazenda
Esplanada dos Ministérios - Bloco P, 4o. Andar
70048-900 Brasília, DF
Phone: 55-61-314-2000
Fax: 55-61-223-5239
Website: <http://www.fazenda.gov.br>

Secretariat of Internatl Revenue Service (SRF)
Secretaria da Receita Federal
Esplanada dos Ministérios, Bloco P
CEP: 70048-900 Brasília, DF
Phone: 55-61-223-4302
Fax: 55-61-321-0488
Website: <http://www.receita.fazenda.gov.br>

American Chambers of Commerce

American Chamber of Commerce Sao Paulo
Rua Alexandre Dumas, 1976
04717-004 Sao Paulo, SP
Phone: 55-11-5180-3804
Fax: 55-11-246-9080
Website: <http://www.amcham.com.br>
E-mail: amhost@amcham.com.br

American Chamber of Commerce Rio de Janeiro
Praça Pio X 15, 5 floor
20040-020 Rio de Janeiro, RJ
Phone: 55-21-203-2477
Fax: 55-21-263-4477
Website: <http://www.amchamrio.com.br>
E-mail: achmbr@amchamrio.com.br

American Chamber of Commerce Salvador
Rua Toquato Bahia, 69 sala 705
Edificio Raimundo Magalhaes
40015-110 - Salvador, BA

Phone: 55-71-242-0077

Fax: 55-71-243-9986

American Chamber of Commerce Minas Gerais

Rua Paraíba, 330/1302

30130-140 Belo Horizonte, MG

Phone: 55/31/273-7347

Fax 55/31/273-4656

Email: amchambr@embratel.net.br

AmchamNet: 011-524-5017 (8N1) 24hrs

Medical Device Trade Associations in Brazil

HOSPITALAR

Rua Oscar Freire, 379 - 19º andar

01426-001 - São Paulo - SP - Brazil

Phone: 55-11-3897-6199

Fax: 55-11-3897-6191

E-mail: hospitalar@hospitalar.com.br

Website: <http://www.hospitalar.com>

Brazilian Association of Importers and Distributors of Medical Equipment and Supplies

Associação Brasileira dos Distribuidores de Equipamentos, Produtos e Suprimentos

Médico-Hospitalares (ABIMED)

Rua Major Diogo, 561, Cj. 1 – Bela Vista

01324-001 Sao Paulo, SP-Brazil

Phone: 55-11-3115-4587

Fax: 55-11-3105-8599

E-mail: abimed@abimed.com.br

Website: <http://www.abimed.org.br>

Brazilian Association of Manufacturers of Hospital, Dental, Medical and Laboratory
Equipment and Supplies

Associação Brasileira da Indústria de Artigos e Equipamentos Médicos, Odontológicos,
Hospitalares e de Laboratórios (ABIMO)

Avenida Paulista, 1313

8º. Andar - Sala 806

CEP 01311-923 - São Paulo

Phone: 55-11-3285-0155

E-mail: abimo@abimo.org.br

Website: <http://www.abimo.org.br>

Brazilian Association of Regulatory Affairs Professionals

Associação Brasileira de Profissionais em Vigilância Sanitária (APPVS)

Av. Brigadeiro Luis Antônio, 2367 - conj. 602

01401-000 - São Paulo – SP

Phone: 55-11-289-4830

E-mail: abpvs@abpvs.com.br

Website: www.abpvs.com.br

Appendix II
U.S. Medical Devices Export to Brazil
(In 1,000 Dollars)

HTS Number	1999	2000	2001	2002	Percent Change 2001- 2002
3005.10.0000 Adhesive dressings and other articles having an adhesive layer	1,024	1,614	2,830	2,765	-2.3%
3005.90.0000 Wadding, gauze, bandages and similar articles, impregnated or coated with pharmaceutical substances for medical, surgical etc purposes nesoi	1,012	744	1,540	786	-49.0%
3006.10.0000 Sterile surgical catgut, similar sterile suture materials and sterile tissue adhesives for surgical wound closure; and similar sterile material	292	740	1,423	2,887	102.8%
3006.40.0000 Dental cements and other dental fillings; bone reconstruction cements	3,165	2,965	9,007	5,965	-33.8%
3006.50.0000 First-aid boxes and kits	6	14	330	205	-37.9%
3407.00.4000 Preparations of dental wax or dental impression compounds; other dental preparations of plaster	268	499	601	311	-48.3%
4015.11.0000 Surgical and medical gloves, of vulcanized rubber other than hard rubber	377	554	67	0*	N/A
*4015.11.0100 Gloves, surgical, of vulcanized rubber except hard rubber	0	0	0	39	N/A

HTS Number	1999	2000	2001	2002	Percent Change 2001-2002
4015.19.0000 Gloves, except surgical and medical gloves, nesoi	203	64	63	*0	N/A
*4015.19.0002 Gloves, mittens, and mitts of vulcanized rubber other than hard rubber, nesoi	0	0	0	23	N/A
6307.20.0000 Other made-up articles including dress patterns: lifejackets and lifebelts	59	164	35	16	-53.8%
6307.90.6500 Other made-up articles, including dress patterns: nesoi surgical drape	51	160	18	52	185.7%
6506.10.0090 Safety headgear, whether or not lined or trimmed, nesoi	888	44	99	60	-40.1%
8419.20.0000 Medical, surgical or laboratory sterilizers	9,456	9,870	7,404	5,048	-31.8%
8419.90.9040 Parts of medical, surgical or laboratory sterilizers	1,151	1,515	2,723	3,024	11.0%
8543.89.8500 Electrical machines and apparatus for electrical nerve stimulation	87	149	24	46	92.5%
8713.90.0000 Invalid carriages, nesoi	25	46	80	25	-68.3%
8714.20.0000 Parts and accessories of invalid carriages	0	19	79	10	-86.8%
9018.11.0040 Electrocardiographs	585	420	1,154	2,198	90.5%
9018.11.0080 Parts and accessories for electrocardiographs	2,490	1,704	1,522	1,564	2.8%

HTS Number	1999	2000	2001	2002	Percent Change 2001-2002
9018.12.0000 Ultrasonic scanning apparatus	32,407	29,720	21,462	31,614	47.3%
9018.13.0000 Magnetic resonance imaging apparatus	17,602	20,753	23,657	12,600	-46.7%
9018.19.4000 Electro-diagnostic apparatus for functional exploratory examination, and parts and accessories thereof	21,587	16,553	16,971	13,085	-22.9%
9018.19.5500 Patient monitoring systems	3,972	4,952	6,045	7,921	31.0%
9018.19.9530 Basal metabolism and blood pressure apparatus	386	896	293	145	-50.5%
9018.19.9535 Electroencephalographs (efg) and electromyographs (emg)	271	77	323	141	-56.2%
9018.19.9550 Electro-diagnostic apparatus, nesoi	9,229	7,075	6,962	4,107	-41.0%
9018.19.9560 Parts and accessories for electro-diagnostic apparatus	7,084	8,223	7,606	4,991	-34.4%
9018.20.0000 Ultraviolet or infrared ray apparatus, and parts and accessories	137	286	183	12	-93.2%
9018.31.0040 Hypodermic syringes, with or without their needles	2,164	228	26	74	185.9%
9018.31.0080 Other syringes, with or without their needles, nesoi	382	395	439	608	38.4%
9018.31.0090 Parts and accessories for syringes, with or without their needles	6,081	2,059	1,177	1,199	1.9%

HTS Number	1999	2000	2001	2002	Percent Change 2001-2002
9018.32.0000 Tubular metal needles and needles for sutures and parts and accessories thereof	445	418	314	336	7.1%
9018.39.0030 Bougies, catheters, drains and sondes and parts and accessories	13,684	14,556	14,491	16,309	12.5%
9018.39.0050 Cannulae and the like and part and accessories	3,857	6,812	5,798	5,125	-11.6%
9018.41.0000 Dental drill engines, whether or not combined on a single base with other dental equipment, and parts and accessories	538	918	147	51	-65.2%
9018.49.0000 Other instruments and appliances, used in dental sciences; and parts and accessories, except dental drill engines, nesoi	3,155	4,701	5,242	3,562	-32.0%
9018.50.0000 Other ophthalmic instruments and appliances and parts and accessories	5,667	9,112	7,061	5,637	-20.2%
9018.90.1500 Optical instruments and appliances and parts and accessories, nesoi	1,046	1,228	1,760	876	-50.2%
9018.90.3000 Anesthetic instruments and appliances and parts and accessories	102	250	1,312	1,051	-19.9%
9018.90.4000 Percussion hammers, stethoscopes and parts of stethoscopes	359	322	816	518	-36.6%

HTS Number	1999	2000	2001	2002	Percent Change 2001-2002
9018.90.5000 Sphygmomanometers, tensimeters and oscillometers; all the foregoing and parts and accessories	64	74	152	25	-83.7%
9018.90.6000 Electro-surgical instruments and appliances and parts and accessories	8,139	11,779	9,198	8,831	-4.0%
9018.90.7020 Dialysis instruments and apparatus	6,182	9,107	19,049	14,236	-25.3%
9018.90.7040 Ultrasonic therapeutic appliances and instruments	115	359	681	770	13.0%
9018.90.7060 Other therapeutic appliances and instruments, except ultrasonic	1,682	1,814	5,036	735	-85.4%
9018.90.7070 Parts and accessories of dialysis instruments and apparatus	2,109	4,065	4,813	3,234	-32.8%
9018.90.7080 Electro-medical instruments and appliances and parts and accessories, nesoi	4,551	4,780	7,652	6,413	-16.2%
9018.90.8000 Other instruments and appliances used in medical, surgical, dental or veterinary sciences, nesoi	20,963	29,657	40,777	30,989	-24.0%
9019.10.2000 Mechano-therapy appliances and massage apparatus; parts and accessories	127	300	531	243	-54.2%
9019.20.0000 Ozone therapy, oxygen therapy, aerosol therapy, artificial respiration or other therapeutic respiration apparatus; parts and accessories	1,783	4,214	4,645	6,126	31.9%

HTS Number	1999	2000	2001	2002	Percent Change 2001-2002
9020.00.8000 Other breathing appliances and gas masks and parts and accessories, nesoi	1,246	1,552	1,277	1,264	-1.0%
9021.10.0050 Bone plates, screws and nails, and other internal fixation devices or appliances	0	0	0	2,440	N/A
9021.10.0090 Orthopedic or fracture appliances and parts and accessories, nesoi	0	0	0	*752	N/A
*9021.11.0000 Artificial joints and parts and accessories	3,938	3,309	2,342	0	-100.0%
*9021.19.4000 Bone plates, screws and nails, and other internal fixation devices or appliances	7,742	6,301	4,143	0	-100.0%
*9021.19.8500 Other orthopedic or fracture appliances and parts and accessories, nesoi	628	720	426	0	-100.0%
9021.21.4000 Artificial teeth of plastic and parts and accessories	160	132	127	161	27.3%
9021.21.8000 Artificial teeth, except of plastic and parts and accessories	53	257	42	20	-53.4%
9021.29.0000 Dental fittings and parts and accessories	640	947	1,327	1,397	5.2%
9021.30.0000 Other artificial parts of the body and parts and accessories	4,818	2,701	1,671	0	-100.0%
9021.31.0000 Artificial joints and parts and accessories thereof	0	0	0	4,264	N/A

HTS Number	1999	2000	2001	2002	Percent Change 2001-2002
9021.40.0000 Hearing aids, excluding parts and accessories	1,479	2,493	1,643	3,579	117.9%
9021.50.0000 Pacemakers for stimulating heart muscles, excluding parts and accessories	6,994	7,133	6,606	8,154	23.4%
9021.90.0000 Other appliances which are worn or carried, or implanted in the body, to compensate for a defect or disability and parts and accessories, nesoi	3,144	5,214	6,649	5,787	-13.0%
9022.12.0000 Computed tomography apparatus	3,154	6,323	14,008	10,312	-26.4%
9022.13.0000 Apparatus base on the use of x-rays for dental, uses, including radiography or radiotherapy apparatus	321	304	1,440	225	-84.3%
9022.14.0000 Apparatus based on the use of x-rays for medical, surgical, or veterinary uses, including radiography or radiotherapy apparatus, nesoi	21,180	10,337	9,379	12,674	35.1%
9022.19.0000 Apparatus based on the use of x-rays for other use, except medical, surgical, dental or veterinary, including radiography or radiotherapy apparatus	1,571	8,367	1,628	2,208	35.7%
9022.21.0000 Apparatus based on the use of alpha, beta or gamma radiations for medical, surgical, dental or veterinary uses	1,084	5,634	2,069	2,376	14.8%

HTS Number	1999	2000	2001	2002	Percent Change 2001-2002
9022.29.8000 Apparatus based on the use of alpha, beta or gamma radiations for other use, nesoi	477	285	688	466	-32.3%
9022.30.0000 X-ray tubes	2,576	3,755	4,379	6,174	41.0%
9022.90.2000 High tension generators, control panels, desks, screens examination or treatment tables, chairs and the like, nesoi	361	59	618	132	-78.7%
9022.90.4000 Parts and accessories of x-ray tubes	168	139	156	160	2.5%
9022.90.6000 Parts and accessories of apparatus based on the use of x-rays	18,202	30,562	43,495	27,217	-37.4%
9022.90.8000 Parts and accessories of high tension generators, control panels, desks, screens examination or treatment tables, chairs & the like, nesoi	1,355	1,544	344	600	74.5%
9025.11.2000 Clinical thermometers liquid-filled, for direct reading	25	0	16	0	-100.0%
9025.19.8040 Clinical thermometers, not combined with other instruments, nesoi	27	8	21	11	-48.5%
9402.10.0000 Dentists', barbers or similar chairs and parts thereof	275	470	81	102	25.1%
Total	280,046	318,267	350,441	300,384	-14.3%

Sources: Statistics have been compiled from tariff and trade data from the U.S. Department of Commerce, the U.S. Treasury, and the U.S. International Trade Commission.

Appendix III

Brazilian Organization: Additional Information

ABIMO - Associação Brasileira da Indústria de Artigos e Equipamentos Médicos, Odontológicos, Hospitalares e de Laboratórios/Brazilian Association of Manufacturers of Hospital, Dental, Medical and Laboratory Equipment and Supplies is the leading trade association for Brazilian manufacturers. ABIMO's approximately 235 members supply more than three quarters of the market [www.abimo.org.br].

ABIMED - Associação Brasileira dos Importadores de Equipamentos, Produtos e Suprimentos Médico-Hospitalares/Brazilian Association of Importers of Medical Equipment and Supplies is the trade association representing importers of medical equipment and supplies in Brazil [www.abimed.org.br].

ANVISA - Agência Nacional de Vigilância Sanitária/Health Regulatory Agency is an independently administered, financially autonomous regulatory agency. Within the Federal Public Administration, the Agency is linked to the Ministry of Health under a Management Contract. ANVISA exercises sanitary control over production and marketing of products and services subject to sanitary surveillance. The agency's charter includes monitoring drug and medical device prices. ANVISA regulations and registration manual are on their website. ANVISA has attended sessions of the Global Harmonization Task Force [www.anvisa.gov.br].

ABRAMGE - Associação Brasileira de Medicina de Grupo/HMO Brazilian Association represents Brazil's HMOs by functioning as an interlocutor with government authorities to find solutions to health issues in Brazil. [www.abramge.com.br].

The Brazilian Hospital Federation (BHF) is a non-profitable association representing the Brazilian hospital net. BHF provides informal business services to its members. The Federation emphasized the importance of importers having a Brazilian tax ID number (CNPJ - Cadastro Nacional de Pessoa Jurídica) as well as having a reliable representative to provide after sale service in the Brazilian market [www.bhf.org.br].

Ministerio da Saude/Ministry of Health (MOH) is the coordinating body of Brazil's health policy. In addition to the public sector, there is a large and wide private health network in Brazil, which complements the services provided by the Government. [www.saude.gov.br/saude].

HOSPITALAR: 10th International Fair for Products, Equipment, Services and Technology for Hospitals, Health Clinics and Laboratories took place in São Paulo, Brazil from June 10 to 13, welcoming more than 65,000 – including a growth of 22% more hospital administrators. HOSPITALAR displays from the most sophisticated state-of-the-art medical technology up to more practical equipment, using local and less advanced solutions, all of these in a wide variety of alternatives in quality and prices. HOSPITALAR is a multi-sector trade fair, featuring 750 Brazilian and international exhibitors, launching products or services and meeting potential and already existing

clients. HOSPITALAR says that in 2002 business volume generated at the fair and as a result of it was around R\$2.7 billion, which represents one fourth of annual sales of the Brazilian medical-hospital equipment industry. HOSPITALAR's next fair will take place in São Paulo, Brazil from June 1 to 4. For further information, please visit HOSPITALAR's website [www.hospitalar.com].

CANDEX do Brazil has been assisting the Brazilian Government (Ministry of Health) in studying the U.S. health/regulatory system to form ANVISA. They help Brazilian authorities in their contacts with North American authorities, organizing high-level trade missions, one-on-one meetings with key regulators, and entrepreneurs both in Brazil and overseas. The group also acts in the intermediation of company mergers, associations, technology transfers, buying and selling products and services overseas, often acting as manufacturers' representatives for market survey and clients locating, and in regulatory affairs issues (product registration and positioning), through our relations with the Health Authorities. [www.candex.us]

ABPVS - Associação Brasileira dos Profissionais em Vigilância Sanitária/Brazilian Association of Regulatory Professionals represents regulatory professionals [www.abpvs.com.br].