MEDICAL DEVICE REGULATORY REQUIREMENTS FOR BRAZIL

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Brazilian National Health Vigilance Agency (ANVISA)

On December 31, 1998 the Brazilian President signed a Provisional Measure # 1791, that created "ANVISA – Agência Nacional de Vigilância Sanitária" (Brazilian National Health Vigilance Agency) and established a new user fees structure for companies and products registration, as set out in the matrix below. The user fees and new certification rules affect medical devices and equipment, pharmaceuticals, vitamins and food products, cosmetics, tobacco and certain sanitation products, which must be registered with ANVISA prior to sale in Brazil. The local representative of the US company should be responsible for the registration of the products.

President Cardoso signed the Presidential Decree #3029 of April 16, 1999, effectively creating the ANVISA and regulating a series of other Provisional Measures and Regulations incorporating the recent negotiations with the Brazilian Congress and the local market. The same Decree, published on the Brazilian Official Gazette on April 27, 1999 sets out the Internal Regulation of ANVISA, according to which the Director President of the Agency is nominated by the President for a five year period of work.

ANVISA is fashioned after the FDA - Food and Drug Administration to substitute SVS - National Secretary of Sanitary Vigilance, instituted by Law # 6360 of 1976. In this new capacity, the new agency has enforcement powers similar to FDA, including cancellation of operation permits for drugs, food and medical product manufacturers and distributors. The Brazilian agency, however, was created as a public company, under a contract to the Health Ministry, therefore is still subject to political guidance from the Health Ministry.

According to an initial analysis conducted by ABPVS – Brazilian Regulatory Affairs Professionals Association, the following are the most important changes resulting from the establishment of ANVISA:

a) Establishes a formal separation between ANVISA which will be responsible for all sanitary and health inspection and the Ministry of Health, which will now be responsible only for public policies related to health issues;
b) Grants ANVISA the power to temporarily intervene in the administration of public companies supplying products or services in the health sector, and considered exclusive or strategic responsibility of the Brazilian government;
c) Cancels Article 58, of Decree-Law 986/69, which exempted imported foods (sold in its original packaging) from registration with the Ministry of Health. In other words, imported food will now be subject to Ministry of Health registration, as has always been the case with local manufacturers. At the government request, the Brazilian

Food Industry Association will be suggesting a list of food additives for colors and preserving food additives which may be exempted from registration;

d) Modifies Article 21 of Law 6.360/76, to state that imported drugs, similar to those manufactured in Brazil, will be automatically registered with the ANVISA after 180 days from the date of filing the registration requirement, if ANVISA fails to accept or reject the product registration within this period of time;
e) Modifies article 20, of Law 6.360/76 to state that no product without clinically or therapeutically proven beneficial substance in its formula, can be registered with the ANVISA;
f) Establishes ANVISA approval for production and registration of tobacco products, hitherto not registered with the Ministry of Health. The cost of registration of a new brand of tobacco, for example will cost US$ 100,000.00 per year;
g) Establishes a new list of registration fees, as outlined below, reviewed by the government in consultation with the industry and effective as of May 10, 1999.

The new legislation defines the following products for which control and registration is mandatory in Brazil:

1. Medications for human use, its active ingredients, and other related materials, processes and technology;
2. Food, including beverages, bottled water, its components, packaging, food additives, organic contamination limits, pesticides and veterinary drugs residues;
3. Cosmetics, personal hygiene products and perfumes;
4. Cleaners, sanitation products for decontamination and hygiene of hospitals, clinics, public transportation and homes;
5. Diagnostic kits, reagents and items for the same purpose;
6. Equipment and materials, devices for hospital, medical, dental, blood banks, laboratory use and image diagnostics;
7. Immune-biological products and their active ingredients, blood and its derivatives;
8. Organs, human and veterinary tissues for transplants or reconstitution;
9. Radioisotopes for in vitro diagnostics, radio-pharmaceuticals and radioactive products used in diagnostics and therapy;
10. Cigarette, cigars and any tobacco product in any form;
11. Any and all products posing any health risks, obtained by genetic engineering, processed or submitted to radiation sources.

ANVISA also enforces its regulations on installations, equipment, technologies, environment and procedures involved in all manufacturing phases of the above items production, their disposal and respective residues.

ANVISA recently published a new device registration protocol, which reflects MERCOSUR-wide policy. The implemented resolution, under number RDC-185 of October 22, 2001, amends previous decree SVS/SAD n. 1 of January 23, 1996. According to the new resolution, an electro-medical manufacturer that requests the equipment registration at ANVISA will have to present he following documents:

a) Medical Products Manufacturer or Importer Form

b) Copy of payment bank receipt (Guia de Recolhimento Bancario) provided by ANVISA

c) Copy of the Facility operation license, issued by local sanitary authority;

d) Copy of the Company working allowance, issued by ANVISA;

e) Copy of technical certification responsibility;

f) Two labels Samples used in the product package;

g) Two instructions copies;

h) Product technical report

i) Copy of Conformity Certification issued by accredited certification organism, in the scope of SINMETRO, proving required specifications adoption as Resolution No 444, August 31, 1999 or proving document issued by SINMETRO certifying the Company's products. (please see IMIs: 1- Resolution 444/99 on Brazilian Medical/Equipment Sector and; 2-Medical Equipment Re-certification in Brazil)

j) Term of information truthfulness responsibility.

Current User Fee Matrix for registration with ANVISA

ITEM	FEE IN R$ (*REAL)**	VALIDITY
1. Operational Authorization for each type of company		
1.1. Drugs manufacturers	20,000.00	Yearly
1.2. Medical products and equipment	10,000.00	Yearly
1.3. Distributors of drugs	15,000.00	Yearly
1.4. Drugstores, pharmacies, and retail shops of medical / hospital products	5,000.00	Yearly
1.5. Any other	6,000.00	Yearly
2. Alteration or increment to the current Authorization (type of activity, company data, joint venture or incorporation)	4,000.00	N/A
3. Substitution of company's legal representative, technical responsible persons or cancellation of authorizations	Exempt	N/A
4. Good Manufacturing Practices and control for each company's office or manufacturing unit, type of activity and production/supply line		
4.1. In Brazil and in the MERCOSUR		
4.1.1. Drugs and pharmaceutical products	15,000.00	Yearly
4.1.2. Medical equipment and products	10,000.00	Yearly
4.1.3. Any other related products	3,000.00	Yearly
4.2. Other countries outside of MERCOSUR	37,000.00	Yearly

5. Registration of		
5.1. Cosmetics	2,500.00	5 Years
5.2.1. Sanitation products - Grade 1 (Minimal) Health Risk	3,000.00	5 Years
5.2.2. Sanitation products – Grade 2 (Potential) Health Risk	8,000.00	5 Years
5.3. Medical Devices		
5.3.1. Equipment (nuclear medicine, computer tomographers, magnetic resonance and cine-angiocoronary devices)	20,000.00	5 Years
5.3.2. Other equipment, instruments and diagnostic kits	8,000.00	5 Years
5.4. Pharmaceuticals		
5.4.1. New drugs (*new formulations*)	80,000.00	5 Years
5.4.2. Similar, or existing formulations	21,000.00	5 Years
5.4.3. Generics	6,000.00	5 Years
5.5. Food and Beverage	6,000.00	5 Years
5.6. Tobacco and similar products	100,000.00	Yearly
6. Increment or modification on the company's registration		
6.1. Packaging details	1,800.00	N/A
6.2. Formula concentration and dosage	1,800.00	N/A
6.3. Prescription text, labeling and packaging	1,800.00	N/A
6.4. Validity or cancellation	Exempt	N/A
6.5. Any other	1,800.00	N/A
7. Exemption of registration	1,800.00	N/A

The above products will have the following discounts for local based companies in the following cases:

a) 15% in case of large Brazilian companies (revenues above R$ 50 million);
b) 30% in case of medium size Brazilian companies, (revenues up to R$ 15 million, as defined by Law 9531 of December 10, 1997);
c) 60% in case of small size Brazilian companies (revenues up to R$ 720,000.00, as defined by Law 9317 of December 5, 1996);
d) 90% in case of "micro-size" (usually very small, sole ownership) companies, (revenues up to R$ 120,000.00, as defined by Law 9317 of December 5, 1996)

* Note: US$/Real exchange rate on the revision date (May 14, 1999), is: US$ 1.00 = R$ 1.70.

As indicated by this matrix, user fees for medical, pharmaceutical and cosmetics products registration represent a significant increase over 1998 levels. For example, registration of a new drug will cost US$ 47,058.00 for each product, and must be renewed every 5 years, a huge increase compared to the old fee of US$ 1,000.00. Registration of products with similar items already in the Brazilian market will be US$ 12,352.94 and generic products, US$ 3,529.41, a clear indication that the government is stimulating the development of the generic drugs market in Brazil. The operational fee for a new pharmaceutical industry will jump from the current US$ 137.50 to US$ 11,764.70, with compulsory annual renewal. Brazilian industry has reacted harshly to the implementation the new user fees. However, most agree that the new agency is a considerable improvement in regulatory affairs and that ANVISA should have its own revenue base.

ANVISA and Brazilian Ministry of Health latest successes were:

- A program called Expande was started by Brazilian Ministry of Health that has the objective to create 20 new high-technology oncology centers (CACONs) that will be equipped to provide diagnostics, clinical and surgical oncology, radiotherapy, haemotherapy and rehabilitation, among other services, under the National Health System (SUS).The total project value is R$ 44 Millions (US$ 19,5 Millions) that will be used until 2004 and the National Cancer Institute (INCA), that is coordinating the program, has already received R$13.7 Million (US$ 6 Million) of the total funding amount since its launch in June 2001. The first CACONs that are already being constructed are in the cities of Divinopolis, State of Minas Gerais; Araguaina, State of Tocantins; Ijui, State of Rio Grande do Sul; Maceio, State of Alagoas and Rio de Janeiro. It is expected that by the end of the year 2002 all of these CACONs be already in operation. Other regions are on analysis for the implementation.

- A second project, called "Program of Modernization and Academic Infra-Structure Consolidation of the IFES and HUS" has the objective to equip all Brazilian Federal Hospitals and Universities. This project is responsible for the purchasing of 285 equipment pieces totaling R$ 227,1 Millions (US$ 100,8 Millions) that will modernize 56 hospitals located in 17 States and Brazilian Federal District. Among other equipment pieces, it was purchased: x-ray machines and Radio-diagnosis angiography machines.

Trade Barriers, including tariffs, non-tariff barriers and import taxes.

Since 1990, Brazil has made substantial progress in reducing traditional border trade barriers (tariffs, import licensing, etc.), even though tariff rates in many areas are still high. Significant non-border trade barriers remain.

In January 1997, the Secretariat of Foreign Trade (SECEX) implemented a computerized trade documentation system (SISCOMEX) to handle import licensing, and a wide variety of products were subject to non-automatic licensing. There are fees assessed per import statement submitted through SISCOMEX, and importers must comply with onerous registration guidelines, including a minimum capital requirement, to register with SECEX (the Foreign Trade Secretariat). Complete information on requirements for importing into Brazil is available only through SISCOMEX, which is only available to registered importers. Beginning in October 1998, Brazil issued a series of administrative measures that required additional sanitary/phyto-sanitary (SPS), quality and safety approvals from various government entities for products subject to non-automatic licenses.

In 1998, in order to fight increasing under-invoicing, Brazil issued a series of measures that required additional approvals for products subject to non-automatic licensing, and broadened the list of such products. While the Government is now in the process of phasing these out and moving most products to the automatic license category, these requirements still present a barrier. Under Brazil's new Customs Valuation regulations, Customs will focus its efforts on under-invoicing, and are authorized to hold up imports until the goods are valued.

A primary concern has been the use of minimum reference prices both as a requirement to obtain import licenses and/or as a base requirement for import. It appears that the Government of Brazil has required some products to meet minimum prices for the issuance of import licenses and/or in order to receive normal customs processing. This would raise questions about whether Brazil's regime is consistent with its obligations under the WTO. In November 1999, the United States actively participated as an interested third party in European WTO consultations on the issue, and in July 2000 the United States held its own WTO consultations with Brazil. The Brazilian Government reportedly has modified its customs regime somewhat, but it has not codified these changes in a public document. Senior Brazilian officials have stated to embassy officers since late 1999 that such requirements currently do not exist.

In addition, product registrations from the Ministry of Health are required for imported processed food products and food supplement products effective March 1, 2000, with a reduced term of validity for registrations. Registration fees for these imports, as well as for medical and pharmaceutical products, also increased significantly over the course of 1999. The U.S. Government also has received complaints relating to Brazil's "law of similarity," including that it leads to non-transparent preferences for Brazilian products in procurement bids for government and non-profit hospitals and prejudices against the import of refurbished medical equipment when domestically-produced "similar" exist. Implementation of such import measures continues to be poorly coordinated and not well publicized, magnifying the negative impact on U.S. exports. In 2001 USCS Medical & Pharmaceutical Team in Brazil had several meetings with SECEX and Brazilian Association for Imported Medical Equipment (ABIMED). Although the Law of Similarity is still an important issue, during the last meeting with SECEX it was suggested that while proceeding medical equipment exportation to Brazil, it is recommended to provide as much information as possible on the product. This information is basis to identify if the product is similar or not to a Brazilian one. Please see related IMI: Law of Similarity.

Tariffs, in general, are the primary instrument in Brazil for regulating imports. The Brazilian applied tariff has 9,371 tariff lines at the eight-digit level, comprising rates of 0 to 35 %. All tariffs are ad valorem, levied on the c.i.f. value of the import, with the exception of some telecommunication goods. Brazil's average applied tariff was 13.7 % in 2000. The average tariff in 1990, by contrast, was 32 %. Brazil also maintains a higher average tariff on processed items than on semi-processed goods and raw materials. The average tariff on finished goods is 15.8 percent, for semi-processed goods 11.9 %, and for raw materials 8.9 %. The United States continues to encourage tariff reductions on products of interest to U.S. firms.

Brazil and its Southern Common Market (MERCOSUR) partners, Argentina, Paraguay and Uruguay, implemented the MERCOSUR Common External Tariff (CET) on January 1, 1995. In November 1997, after consulting with its MERCOSUR partners, Brazil implemented an across-the-board three-percentage point increase on all tariffs (inside and outside the CET), raising the ceiling from 20 to 23 %. Only energy inputs such as coal and petroleum and agricultural inputs such as seeds were exempted. Although Brazil had agreed with other MERCOSUR members to end the temporary three-percentage point increase beginning January 2001, a more modest reduction schedule has been implemented. A half percentage point decrease was agreed to by MERCOSUR members effective January 2001, and an additional one percentage point decrease will take place on January 1, 2002, with the remaining one percentage point likely ending sometime in 2002-2003.

In early 2001, the CET covered approximately 85 % of 9,500 tariff items, with most of the remaining items scheduled to be covered during 2001, and full coverage by 2006. The CET levels range between zero and a maximum of 23 %, with the exception of tariffs on Brazil's national list of exceptions to the CET, such as shoes, automobiles and consumer electronics, and telecommunications equipment, computers, and some capital goods. The rates for the latter three product groups are scheduled to conform to the CET by the year 2006, at which time the maximum rates will be 14 % for capital goods and 16 % for computers and telecommunications equipment. The tariff rates for these goods are generally higher than average. However, in March 2001 a waiver was given to Argentina, in the face of severe economic difficulties, to temporarily raise extra-bloc tariffs on a large number of consumer goods to 35 % and reduce tariffs on a large number of capital goods to zero. Given this development, the CET is currently full of exceptions. With the exception of sugar and automobiles and parts, trade between Brazil and Argentina is duty free.

The United States signed a trade and investment framework agreement with this emerging common market in 1991. The United States will continue to encourage the reduction of barriers to trade and investment, including tariffs and the creation of a customs union that is open and consistent with the WTO, specifically GATT Article XXIV.

Tax and Fees Assessed on Imports

Imports are subject to a number of taxes and fees in Brazil, which are usually paid during the customs clearance process. There are three main taxes that account for the bulk of importing costs -- (1) Import Duty itself (known in Brazil as the "II"), (2) the Industrialized Product tax (known in Brazil as the "IPI"), and (3) the Merchandise and Service Circulation tax (known in Brazil as the "ICMS"). Please note that most taxes are calculated on a cumulative basis. In addition to these three taxes, several other taxes and fees apply to imports; such costs are discussed below.

- Import Duty

  Import duty is a federally mandated product specific tax. After the creation of the MERCOSUR customs union, the four member countries -- i.e., Argentina, Brazil, Paraguay and Uruguay -- adopted a single import tariff structure known as the "common external tariff" (known in Brazil as the "TEC"). While after the adoption of the TEC, Brazilian import tariff rates were reduced, they are still high in comparison to U.S. import tariff rates. In most cases, Brazilian import duty rates range from 10 - 20 %.

- Industrialized Product Tax (IPI)

  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 IPI tax is not considered a cost for the importer, since the value is credited to the importer. Specifically, when the product is sold to the end user, the importer debits the IPI cost.

The Government of Brazil levies the IPI rate by determining how essential the product may be for the Brazilian end-user. Generally, the IPI tax rate ranges from 0 to 15 %. In the case of imports, the tax is charged on the product's c.i.f. value plus import duty. Often one can note that usually a relatively low import tariff rate carries a lower IPI rate. Conversely, a relatively high import tariff rate carries a correspondingly higher IPI rate. As with value-added taxes in Europe, IPI taxes on products that pass through several stages of processing can be adjusted to compensate for IPI taxes paid at each stage. Brazilian exports are exempt from the IPI tax.

- Merchandise and Service Circulation Tax (ICMS)

  The ICMS is a state government value-added tax applicable to both imports and domestic products. The ICMS tax on imports is assessed *ad valorem* on the c.i.f. value, plus import duty, plus IPI. 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 paid value 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 tax is paid only on the value-added, 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 by companies 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. The rate varies among states, in the State of Sao Paulo, the rate is 18 percent. On interstate movements, the tax will be assessed at the rate applicable in the state of destination. (Some sectors of the economy, such as construction services, mining, electrical energy, liquid and gaseous fuels are exempt from the ICMS tax. Most Brazilian exports are exempt.)

- Additional Miscellaneous Taxes and Fees

  - Warehouse Tax: 0.65% of CIF for a 15 day period
  - Typical Terminal Handling Charges at Santos' port: US$100 per container
  - Merchant Marine Tax: 25% of ocean freight charges (does not apply to air freight)
  - Mandatory Contribution to Custom Broker's union: 2.2% of CIF with a minimum contribution of US$71 and a ceiling set at US$160
  - SISCOMEX usage fee: US$30
  - Typical Cargo Transportation Fee: US$35

The hypothetical cost buildup for an imported machine, shipped in a 20 foot container, shipped from Miami to the port of Santos illustrates how taxes and fees are calculated. It also illustrates the impact of importing costs on the landed price of the product in the Brazilian market.

FOB price of Product	**100,000**
*Freight	2,400
Insurance (1%)	1,000
CIF Price of Product	**103,400**
Import Duty Rate: 19% -- applied to CIF	19,646
IPI: 5% -- applied to CIF + import duty	6,152
ICMS: 18% -- applied to CIF + import duty + IPI	23,256
Merchant Marine Tax: 25% of ocean freight cost	600
Warehouse: 0.65% of CIF; or min. US$ 170, max US$ 235	235
Terminal Handling Charges: average US$ 100 per container	100
Contribution to Custom Broker's union 2.2% CIF; or min of US$ 71, max US$ 160	160
Custom Brokerage Fee: average 0.65% of CIF or min US$ 170, max US$ 450	450
SISCOMEX Fee	30
Typical Cargo Transportation charge	35
Typical Bank Costs: 2% of FOB	2,000
FINAL COST	**156,064**

Health and Pharmaceutical Products Exempt from Import Duties and VAT taxes

To lower the cost of medical device imports, the Brazilian government reduced the import duties and VAT taxes 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
- 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, intra-ocular lenses)
- Other - automatic defibrillators

Standards

Brazil usually accepts U.S. product standards and certifications by U.S. testing laboratories such as Underwriters Laboratory.

State of Espírito Santo Tax Exemption Incentive

Until very recently, Brazilian states were very aggressive in terms of offering incentives to attract new business to their regions. Some called the competition a virtual "fiscal war." Even though the approaches to attract business and trade have changed, some Brazilian states still provide fiscal incentives that may have an impact on business decisions. For example, the selection of a port may have an impact on importing costs. In the State of Espirito Santo which borders the states of Minas Gerais and Rio de Janeiro there is an incentive program for imports that come through the state's ports. It allows importers to postpone the payment of sales tax (known as the ICMS) for a period up to 70 days. Moreover, for shipments staying in the state, the sales tax rate is reduced from 17 to 12 %.

Customs Regulations

In 1997 the Brazilian Government established a computerized information system to monitor imports and to facilitate customs clearance known as the Foreign Trade Integrated System (SISCOMEX). The SISCOMEX has facilitated and reduced the amount of paperwork previously required for importing into Brazil, which, however, can still be burdensome. Brazilian importers must be registered in the Foreign Trade Secretariat - SECEX's Export and Import Registry and receive a password given by Customs to operate the SISCOMEX. The SISCOMEX has a graphic interface for the composition of electronic import documents and transmits information to a central computer.

Customs Clearance in Brazil can be a time consuming and frustrating process, similar to other countries in the region. In a report issued by the ICEX (Instituto de Estudos das Operações de Comércio Exterior) in 1999 year 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 of emissions in paperwork. In FTAA negotiations, Brazil and the U.S. are working on measures to allow more rapid customs clearance. The Brazilians recognize that many of its ports, loading and unloading as well as customs clearance need increased efficiency. To this end, they are also working on a "green line" expedited method of clearance. However, you should be prepared for the fact that unloading and clearance may take substantially longer than expected.

Import Licenses

- *Automatic License*

As a general rule, Brazilian imports are subject to the "automatic import license" process.

This procedure requires that the Brazilian importer submits information concerning each import, including description of the product as well as the harmonized tariff classification number, quantity, value of the shipment, shipping costs, etc. This information will be used for purposes of preparing the "Import Declaration" (locally known as the DI). Subsequently, all information is fed into Brazil's customs computer system known as the SISCOMEX. The Brazilian Foreign Trade Secretariat (SECEX) is the government agency responsible for granting import licenses. Certain products and import operations

are subject to special requirements, which should also be completed prior to the customs clearance process. Below is an illustrative list of special requirements.

- Approval by Brazil's Agricultural Ministry for imports of meat and food products, sea food products, milk and milk derivatives, eggs and honey, fruits, and several other animal or vegetal products;

- The Brazilian Environmental Protection Agency may need to issue a determination concerning imports of natural, synthetic or artificial rubber;

- Company and/or product registration may be required for imports of numbers for asbestos, agricultural chemicals, pharmaceutical products, perfumes and cosmetics and medical related products.

- *Non-Automatic License (LI)*

Whenever imports are subject to the Non-Automatic License (LI) regime, the importer must provide information concerning each shipment to Brazilian customs authority either prior to shipment or prior to customs clearance. The required information includes a description of the product as well as the harmonized tariff classification number, quantity, value of the shipment, shipping costs, etc.

Prior to Customs Clearance: Products imported under the drawback regime, as well as imports destined to the free trade zones and the National Council for Scientific and Technological Development.

Prior to Shipment Clearance: Products subject to special controls from SECEX or which require approvals from other Brazilian government agencies. Such products may include:

- products subject to import quotas (tariff and non-tariff);
- subject to similarity audit;
- used products;
- products that enjoy import tariff reductions;
- imports that do not involve payment from importer to the exporter (samples, donations, replacement of goods, leasing, rental, foreign investments, temporary admission)
- products that affect human nervous functions;
- narcotics, psychotherapeutic drugs, etc.;
- products for human or veterinary research;
- weapons and related products;
- radioactive products and rare earth metal compounds;
- crude oil, oil derivatives or other petroleum derivatives;
- anti-hemophilic serum, medications with plasma and human blood;
- products that may be harmful to the environment, as CFC;
- skins and leathers as well as finished products;
- mailing machines, stamp selling machines, as well as parts and pieces;
- airplanes, spatial devices as well as parts and pieces;
- products subject to specific price controls or payment term controls.

Shortly after feeding the SISCOMEX system information concerning a specific shipment, the SISCOMEX system will indicate whether or not a "non-automatic import license" is required.

Export Controls

At this time, the U.S. Government maintains no export controls specific to Brazil. Normal controls are maintained on military equipment and high-tech information systems and equipment of a highly sensitive nature. For additional information, please contact the U.S. Trade Information Center at 1-800-USA-TRADE.

Import/Export Documentation
(Health, Pharmaceuticals, Pre-shipment Inspection).

Any product that comes in contact with the human body is controlled by the Ministry of Health (MOH), including pharmaceuticals, vitamins, cosmetics and medical equipment/devices. Such products can only be imported and sold in Brazil if:

- The foreign company establishes a local Brazilian manufacturing unit or local office; or

- The foreign company appoints a Brazilian distributor who is authorized by the Brazilian authorities to import and distribute medical products. However, such products must be registered with the Brazilian Ministry of Health.

Note: Any and all products related to health, applied to the skin, injected into the body or even inserted into the eye (contact lens and cleaning liquids, for example), and any other having a medical application have to be registered with the MOH.

Documents Required of Local Distributors for Product Registration, Importation and Sales in Brazil

a) "Alvará de Funcionamento" - A trading permit granted by the state sanitary authorities. This allows the company to import, distribute, store and sell the product registered with the SVS.

b) "Autorização de Funcionamento" - A permit like the "Alvará de Funcionamento", but granted by the Federal Government.

c) Contract with a qualified technician (such as a chemist, pharmacist, engineer, etc, according to different types of industry). This is called "Terms of Technical Responsibility", signed by the professional. This document can be obtained from the Regional Pharmaceutical Council.

d) Contract with a local Brazilian laboratory to do the quality control certificate for each one of the products to be registered. This laboratory must be an "OCC-Organismo de Controle e Certificação", (Control and Certification Laboratory) an official registered certification 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 Ministry of Health.

Product Registration

Product registration in Brazil is a laborious exercise, and has to be requested by the local office of the foreign company, or its agent. The registration is valid for five years and can be renewed continuously for the same period. Exceptions are: diet products that are valid only for two years and can also be renewed for an additional 2-year period. The registration process must be completed within 90 days after the registration is requested. The foreign company should take a series of measures in order to guarantee its rights to the registration, including:

* Apply for registration of the trademark and patent with the INPI - National Industrial Property Institute, through a local law firm.

* Establish a solid contract with the distributor to protect the manufacturer's rights, including the ownership of its registration with the Ministry of Health. This should be done through a local agent.

* It is also recommended that the foreign company establish specific clauses on the contract, transferring the ownership of the registration from the agent to the manufacturer, thus minimizing risks. This transference can only occur if the foreign company opens an office or plant in Brazil, since no registration can be transferred overseas. Transfer to another agent is extremely difficult to obtain.

* Manufacturers have to disclose to the 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

Manufacturers have to disclose to the local authorities, through their agents, the technical information of the product, e.g., components and parts of the medical devices. In the case of pharmaceutical drugs and cosmetics, one must inform the active and inactive ingredients. Instructions, directions, cautions, labels, brochures, and pertinent information about the products must be translated into Portuguese.

The product registration process often takes more than one year. Should the process take longer than three months, importers and producers are allowed to use a protocol number provided by the Brazilian authorities and distribute their products in Brazil. However, by doing so they assume the risk of product liability claims if their products are found to be unsafe by the Brazilian authorities.

The following information is required for registration of medical devices:

- Name of company
- Address
- Product name
- Product Description
- Legalized FDA Certificate to Foreign Government (CFG)

- Final Product Drawings
- List of Components/Materials
- Manufacturing Method (Flow Chart)
- Labels/Directions for Use
- Sterilization Parameters
- Quality Control Test Methods/Records
- Clinical Publications
- Product Brochure (Catalog Page)

Additional documents required for MERCOSUR registration:

- Letter of Authorization
- Packaging Materials
- Quality Control Certificate
- Biocompatibility Reports
- FDA status

Types of Product Registration

For registration purposes, SVS classifies the products in the following categories:
1. Drugs**:** substances for medical or sanitary use (like sanitizing agents).
2. Medicine: curative, preventive or diagnostic pharmaceutical products.
3. Pharmaceutical Raw Materials: drugs or raw materials to be used in medicines
4. Food: Prepared food products
5. Related Products (Correlates): other than the above definitions. The following products and substances used to protect health, for personal hygiene and cleanliness: medical products, cosmetics, perfumes, dietary, dental and veterinary products, insecticides and poisons.

According to Brazilian Law 6360 of 1976 and its addition number 74.094 of 1977 and Administrative Act number 71/96, and other regulations from the Ministry of Health, products that have to be registered, in addition to medical and pharmaceutical items, are:

- Cosmetics
- Child products (lotions, etc)
- Perfumes
- Hygiene products

Cosmetic products are classified according to the health risk they may present.

Grade 1 products are products with minimal risk, such as: soaps; shampoos; tooth pastes and deodorants; shaving creams; after shaving lotions; tooth brushes; dental floss; powders; beauty creams; facial masks; beauty lotions; oils; make-up; lipstick; lip pencils and liners; eye products; and perfumes.

Grade 2 products are products that present potential risk, such as: hair colors; hair lighteners; hair perming and straighteners; products for hair and scalp

treatment (anti-dandruff shampoos); chemical depilatories; insect repellents; and products for children.

Although the same documentation is required for grade 1 and 2 products, the registration of grade 1 products is much faster and simpler than the registration of grade 2 products.

Documentation Needed for Registration

The essential basic documents required from the local agent of the foreign company for the registration of products in Brazil are:

a) Application form obtained from the Brazilian Ministry of Health;
b) Original copy of the machine stamped bank slip, which serves as proof of registration fee payment;
c) Trade Permit ("Alvará de Funcionamento") issued by the State authority to the manufacturer's distributor;
d) Same type of document ("Autorização de Funcionamento"), issued by the Federal authority to the manufacturer's distributor;
e) Document showing the technical responsibility of the distributor/ manufacturer, issued by the certification entity;
f) Technical Report on the product, informing the components of the formula, instructions, directions, cautions, etc;
g) Label sample, brochures, pertinent information about the products, all translated into Portuguese;
h) For products not clearly mentioned on the Brazilian law, it is mandatory to provide information about their utilization, in order to demonstrate its efficacy and safety;
l) Copy of the registration granted to the products at the country of origin (or copy of the Free Sale Certificate);
j) Copy of legal document, by which the manufacturer authorizes its distributor to trade and distribute the products.
k) If a medical equipment, all documents showing product safety, country of origin, detailed (exploded view) of the equipment inner parts and user manual, have to be presented for registration.

Note: Among the above requirements, special attention should be paid to the TECHNICAL REPORT. This is mentioned on Administrative Act 71/96, and which requires from the cosmetics, vitamin, pharmaceutical manufacturer:

1. The complete description of the product's formula, with all the components specified by their chemical designation, and the quantities of each one of them expressed in the metric system;
2. Inform the function of each component, and its function as integral part of the formula;
3. Name the components according to the Pharmacopoeia Standards, Brazilian and International Compendia or attached bibliography, discussing the component and pertinent literature, including safety rules and efficacy. This information must be translated into Portuguese.

Product registration often takes more than one year. However should the process take longer than three months, importers and producers are allowed to use the protocol number provided by the Sanitary Inspection Secretariat to distribute their products in Brazil. However, by doing so they assume the risk of product liability claims if their products are found to be unsafe by the Secretariat.

According to Brazilian importers, the price for registering a cosmetic product or perfume in Brazil is about US$ 600, of which US$ 220 is the cost of the "despachante" (a local agent who is paid to handle the paperwork, submit documents etc.). Medical products vary, depending on specific types of equipment. It is advisable that the local U.S. exporter's representatives do use established product registration agents, particularly if the representative is new to the market or does not have adequate knowledge of this process (which can be complicated). U.S. exporters can attain additional information and local contact agents through ABPVS – Brazilian Sanitary Inspection Professionals Association.

Temporary Goods Entry Requirements

On December 20, 1999, Brazilian Customs issued regulation 150 (Instrução Normativa 150) establishing new procedures for imports under Temporary Admission Program. The Program allows for imports of goods for a pre-determined time frame and a clear objective. Under the program, import tax and the Federal tax (IPI) are only charged on products that will be used in the production of other products and involves payment of rental or lease from the local importer to the international exporter. This includes products such as dies, matrixes, sheets and industrial tools. Due taxes are proportional to the time frame the imported product will remain in Brazil.

The import tax applicable on products imported under temporary admission program is calculated according to the following formula:

$$V = I \times \left[1 - \left(\frac{12 \times U - P}{12 \times U}\right)\right]$$

V = the tax to be paid
I = Federal Taxes in the normal import process
P = number of months in which the product will remain in Brazil
U = the life span of the product - according to Normative Instruction # 162, dated December 31, 1998)

An example is a leasing operation for 12 months of a US$ 200,000 machine into Brazil, with 10% import tariff and 5% tax over industrial product (IPI). The life span of this hypothetical machine is 5 years. In a regular operation the due taxes would be as follows:

CIF Price:	200,000
Import Tax:	20,000
IPI:	11,000 (5% over CIF Price + Import Tax)

Payable taxes: US$ 31,000
Under the temporary admission program payable taxes would be as follows:

$$V = 31000 \times \frac{[1-\{12 \times 5 - 12\}]}{12 \times 5}$$

$V = 31000 \times [1 - 0.8]$
$V = 31000 \times 0.2$
$V = 6200$
$V = US\$\ 6200$

Labeling, Marking Requirements

The Brazilian Customer Protection code, in effect since September 12, 1990, requires that product labeling provide the consumer with correct, clear, precise, and easily readable information about the product's quality, quantity, composition, price, guarantee, shelf life, origin, and risks to the consumer's health and safety. Imported products should bear a Portuguese translation of this information. Since metric units are the official measuring system, products should be labeled in metric units or show a metric equivalent. The labeling requirement for genetically modified organism (GMO) must follow the same procedures as mentioned above, although, GMO is currently being debated in Brazil.

The United States Senate Concurrent Resolution nº 40 adopted July 30, 1953, invited U.S. exporters to inscribe, on external shipping containers in indelible print of a suitable size. "United States of America". Although such marking is not compulsory under law, U.S. shippers are urged to follow this procedure in publicizing American-made goods.

Information sources:

IPEM – Instituto de Pesos e Medidas do Estado de São Paulo
Rua Muriaé, 154 Alto do Ipiranga
Cep: 04260-900 São Paulo, SP
Phonefax: 55/11/ 5069-0300
Website: www.ipem.sp.gov.br

- National Health Vigilance Agency (ANVISA)
  Agencia Nacional de Vigilancia Sanitaria (ANVISA)

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70770-502 Brasilia/DF-Brazil
Phone: +55 61/-448-1458
Fax: +55 61/-448-1031
website: http://www.anvisa.gov.br

Prohibited Imports

The Brazilian Government has eliminated most import prohibitions. However, it places special controls on certain imports and prohibits the importation of others, e.g. pleasure

boats valued above US$ 3,500. The importation of used machinery, automobiles, clothing, and many consumer goods continues to be severely restricted. Imports of some used machinery, however, have been authorized under special exemptions. Court decisions have challenged the regulation that bans used car imports. Imports of used machinery and equipment to the Manaus Free Trade Zone are subject to more liberal treatment.

Standards

Technical Regulations. In regulated sectors, the appropriate agencies impose their own requirements, ranging from registration of products and laboratories to mandatory certification with the 3rd party testing done in-country.

Brazil has in place a number of regulations that are being reinforced. Most newly published rules mandate compliance to safety requirements with evidence of compliance often, but not exclusively, through mandatory product certification. With renovated regulations, it is expected that enforcement will increase.

Legal framework**.** Federal law established in 1973 the National System of Metrology, Standardization and Industrial Quality, SINMETRO, with involvement from public and private organizations. ABNT, the Brazilian Association for Technical Standards (Associaçao Brasilera de Normas Técnicas), is the recognized standards organization. INMETRO, a government entity, is the national accreditation body, is responsible for all aspects of metrology and is the operating arm of CONMETRO, the national committee that oversees the work of SINMETRO.

Voluntary Standards**.** National voluntary standards in all sectors are developed by ABNT. In some areas, ABNT bases its standards on those of ISO and IEC and on occasion on U.S. standards. ABNT is also a certification organization for both products and systems.

In Brazil, many standards are voluntary. The buyer and seller share responsibility in determining what product standard is applicable. Products conforming to US standards may be fully acceptable. However, products that meet European requirements may be preferred. This preference may be expressed in procurement specifications or in customary design and construction practices.

Given the growing importance of standards and conformity assessment in expanding U.S. exports, a standards expert has been assigned to work in the Commercial Service, at the U.S. Embassy in Brasilia, with regional responsibilities for South American countries.

Testing and Product Certification. There is no legal mandate to date to retest non-regulated products that have been approved in their country of origin. For non-regulated products, some U.S. marks and product certification may be accepted. As with standards, any certification that may be required in non-regulated sectors is a contractual matter to be decided between the buyer and the seller.

For regulated products, on the other hand, the relevant government agency generally requires that the entities that engage in mandatory certification (regulated products)

must be accredited by INMETRO. Testing laboratories must similarly be accredited. Testing must generally be performed in country unless the needed capability does not exist in Brazil.

To facilitate the acceptance of U.S. products in the Brazilian market, agreements between U.S. and local certifiers and testing houses are encouraged. This could provide recognition of existing certifications. Also, there is no impediment for U.S. certification organizations to be established and accredited in Brazil.

Future trends. Brazil has developed national planning documents for standards and certification activities that indicate the sectors where activities will be focused.

Standards and Regulations in MERCOSUR. Brazil, as an active MERCOSUR member, participates in the development of both MERCOSUR standards and regulations.

MERCOSUR standards are developed by a committee where the private sector standards institutes of Argentina, Brazil, Paraguay and Uruguay are represented. The MERCOSUR Standards Association has an Executive Secretariat located in Sao Paulo. Most of the voluntary standards published deal with steel products and cement and concrete. Several hundred additional standards are at different stages of preparation or in the work plan with many in the electrical safety area.

Regional technical regulations are developed and/or harmonized within the MERCOSUR Sub Working Group 3 in the following fields: automotive, foods, metrology, safety of electrical products, toys and others. Other working groups are focused on telecommunications and health issues. To be applicable, harmonized MERCOSUR regulations must be adopted by each country.

International Agreements. Brazil, a member of the World Trade Organization (WTO), signed the TBT agreement on Technical Barriers to Trade, affirming its WTO obligations to use international standards to the maximum extent possible. Responsibilities under the TBT agreement include the establishment of a national inquiry point to serve as a central location for information on standards-related issues, including proposed mandatory regulations. The Brazilian inquiry point is in INMETRO in Rio de Janeiro. The US inquiry point is the NCSCI, located at NIST.

For information on Brazilian and MERCOSUR standards, please contact:

ABNT - Associação Brasileira de Normas Técnicas
Av. Treze de Maio 13 – 27 Andar
20003 900 Rio de Janeiro – RJ
Brazil
Phone: (55-21) 210-3122
Fax: (55-21) 240-8249
Website: http://www.abnt.org.br

Asociacion Mercosur de Normalizacion
Av. Mario de Andrade 664
01154-060 Sao Paulo – SP (Brazil)
Phone: (55-11) 823-9846/42
Fax: (55-11) 823-9689

E-mail: secexecmn@target.com.br

For information on the WTO-TBT inquiry point, contact:

INMETRO – Instituto Nacional de Metrologia, Normalização e Qualidade Industrial
Rua Santa Alexandrina 416, Rio Comprido
20261-232 Rio de Janeiro – RJ
Brazil
Phone: (55-21) 502-1009
Fax: (55-21) 502-6542
Website: http://www.inmetro.gov.br

For information in the U.S., please contact:

National Center for Standards and Certification Information (NCSCI)
National Institute of Standards and Technology (NIST)

Unit 3500, APO AA 34030	*or*	Gaithersburg, MD 20899
Phone: +55 61/ 312-7340 / 312-7000		Phone: (301) 975-4038
Fax: +55 61/ 225-3981		Fax: (301) 926-1559
e-Mail: Avi.Braganca@mail.doc.gov		e-Mail: ncsci@nist.gov

American National Standards Institute (ANSI)
11 West 42nd Street
New York, NY 10036
Phone: (212) 642-4900
Fax: (212) 398-0023
Web Site: http://ansi.org

Free Trade Zones/Warehouses

As of May 1994, there are four free trade zones in Brazil -- Manaus, in the State of Amazonas; Macapá/Santana, in the State of Amapá; Tabatinga, in the state of Amazonas, which borders Peru; and Guajaramirim, in the State of Rondônia, bordering Bolivia. Four other free trade zones are authorized but not yet functioning -- Bonfim and Paracaíma in the state of Roraima, Brasiléia in the State of Acre and Epitaciolândia in the State of Rondônia.

The Manaus Free Trade Zone is the most extensively developed. Decree No. 288 of February 1967 established special incentives for a period of 30 years with the aim of creating an industrial, commercial and agricultural center in the heart of the Brazilian Amazon. The Manaus Free Trade Zone is a 10,000 square kilometer area which includes the city of Manaus, the capital of the State of Amazonas in the north of Brazil. Unlike Manaus, which has special incentives for the establishment of industries, the other zones are only free ports for imports and exports.

The Brazilian Constitution of 1988 endorsed the fiscal benefits of the Manaus Free Trade Zone and extended their applicability to the year 2013. Free Trade Zone status implies that goods of foreign origin may enter into the Manaus free port without payment of customs duties or other federal, state or local import taxes. In addition, the Industrial Products Tax (IPI) on certain commodities and the ICMS sales tax on most items are not applied. With very few exceptions imported products used for processing, re-export or

transshipment which are subsequently shipped to other parts of Brazil also qualify for these tax exemptions. The ICMS sales tax is imposed on items produced in the free port when they are shipped out of the free zone into other areas of Brazil.

Law No. 8387 of December 30, 1991, modified the regulations for the Manaus Free Trade Zone by eliminating the previously existing import quota and requiring only that prior notification is made to the Superintendent of the Manaus Free Zone (SUFRAMA). However, in May 1995 the Brazilian Government returned to the import quota system and presently only imports of wheat and petroleum are not subject to quotas.

Manaus Free Trade Zone importers are allowed to supply foreign goods from their stock in Manaus to other parts of the country regardless of quantity. These goods, however, are subject to all duties assessed under normal importation. There is, however, the advantage that the ICMS (Merchandise Circulation Tax) is reduced to only 4 percent.

The Manaus Free Trade Zone was hard hit by the general lowering of tariff and non-tariff barriers. In July 1992 the government announced a series of measures to help the Manaus Free Trade Zone. Each industry must perform certain basic assembly steps in the zone in order to qualify for fiscal incentives. To protect Manaus industries, such as consumer electronics, which are heavily concentrated in the zone, the Tax on Industrialized Products (IPI) was raised by ten percentage points on competing products which are either imported from abroad or produced in Brazil outside the zone. The initial list included stereos, televisions, and VCRs, none of which are produced in Brazil outside the zone. Computers and peripherals were not on the list.

Fiscal incentives for Manaus include exemption from the IPI tax and from tariffs on imported components, reduced tariffs on products shipped from Manaus to the rest of Brazil; reduced state tax (ICMS) on products imported from or exported to the rest of Brazil, up to ten years exemption from federal income tax, and an exemption from import license fees.

The 1992 regulations allowed computer firms to benefit from both fiscal benefits and the change in local content requirements. With special government permission, computer firms, although required to perform much basic assembly in the zone, may be permitted to import circuit boards which use only surface mounted devices.

SECEX import licenses, issued through SISCOMEX, must be issued prior to shipment of goods destined for the Brazilian marketplace. These licenses are additionally subject to authorization by the Superintendent of the Manaus Free Trade Zone (SUFRAMA), the Manaus free zone authority. Commercial invoices and bills of lading must have "Free Zone of Manaus" typed on them, and one of the following statements: "Zona Franca de Manaus para Consumo" (Manaus Free Zone for Consumption) or "Zona Franca de Manaus para Reexportação" (Manaus Free Zone for Reexport).

Brazilian restrictions on the informatics sector no longer apply to the Manaus Trade Zone. A license and an authorization requirement for health/sanitary controls, national security interests, and environmental protection remain in effect.

Each passenger leaving Manaus is allowed a quota of US$ 2,000 (FOB value) of goods of foreign origin. Products manufactured in Manaus are not subject to the quota.

In addition to the free trade zones, 14 export processing zones have been authorized. The Ministry of Industry, Commerce and Tourism administers them. To date, only four have begun initial infrastructure construction; the remainder is still in the planning stages.

Legislation regarding ZPEs requires that firms operating in the zone export at least 90 percent of production. Up to 10 percent of production can be sold in the domestic market, and is subject to a duty of 75 percent ad valorem on the final price, minus the cost of imported inputs. Normal corporate income taxes apply to profits generated in the zones. Firms operating in the zones will be exempt from foreign exchange regulations and will maintain dollar and local currency accounts. The official Brazilian exchange rate must be used to convert dollar accounts for local purchases. Foreign firms established in the zones may use their own hard-currency resources for tax-free imports of machinery and raw materials from abroad. Firms in the ZPE may not produce goods subject to export quotas. License and authorization requirements remain in effect in ZPEs for health/sanitary controls, national security interests, and environmental protection.

Membership in Free Trade Arrangements

Brazil is a founding member of MERCOSUR, the Southern Common Market, a member of the World Trade Organization, and a participant in negotiations that would establish a Free Trade Area of the Americas by December 2005. An imperfect Customs Union, MERCOSUR members Brazil, Argentina, Paraguay, and Uruguay implemented a Common External Tariff (CET) on January 1, 1995. (see discussion under tariffs for further details on the MERCOSUR CET). Chile and Bolivia joined MERCOSUR as associate members in 1996.

Contact Information

Governmental Agencies

- U.S. Embassy Brasilia,
  U.S. Department of Commerce – Brasilia Office

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- U.S. Department of Commerce – São Paulo Office

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- National Health Vigilance Agency (ANVISA)
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- Ministry of Development, Industry, and Foreign Trade (MDIC)
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  Secretaria de Comercio Exterior (SECEX)
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- Ministry of Development, Industry, and Foreign Trade (MDIC)
  Ministerio do Desenvolvimento, Industria, e do Comercio Exterior (MDIC)
  Department of Foreign Trade Operations (DECEX)
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Phone: 55 21/ 3849-1305 / 3849-1306

- Ministry of Finance (Tariff Queries)
  Ministerio da Fazenda

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Fax: 55 61/ 223-5239
site: http://www.fazenda.gov.br/

- Ministry of Health
  Ministerio da Saude

Contact: Mr. Barjas Negri
Minister

Address: Esplanada dos Ministerios - Bloco G, 5o. Andar
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Phone: 55 61/ 315-2425
Fax: 55 61/ 224-8747
Site: http://www.ms.gov.br/

Active Domestic Industry Representatives

- Brazilian Medical Devise Importers Association (ABIMED)
  Associacao Brasileira de Importadores de Produtos Medicos (ABIMED)

Contact: Mr. Jose Manuel Laranjeiras
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Fax: +55 11/ 3105-8599
e-Mail: abimed@abimed.com.br
Site: http://www.abimed.com.br

- GE – General Electric Medical Devices

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Site: http://www.ge.com.br

- Varian Inc.

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Site: http://www.varianinc.com.br

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-

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