Ministry of Foreign Affairs

Market Report Life Sciences for Human Health in Argentina

Commissioned by the Netherlands Enterprise Agency

>> *Sustainable. Agricultural. Innovative. International.*

Market Report
Life Sciences for Human Health
in Argentina

Introduction (why this market report)

The Netherlands holds strong capabilities in the area of the life sciences, including those in the sector of human health and its equipment and software subsectors.

The Netherlands is the third largest world exporter of medical devices, behind the US and Germany. It exported worldwide USD 9.5 Bn in 2018[1]. One of the largest global biomedical technology companies, Philipps is based in the Netherlands (and is present in Argentina since 1935).

As a result from the Covid 19 pandemic there has been a renewed interest globally on the medical procedures that use higher technology to contain and treat human deseases. An example are the amount of studies underway in the search for a vacccination against the virus, of over 100 initiatives worldwide.

In Argentina a new national government has repeatedly indicated its goal of supporting local technology development, from the Ministry of Productive Development and also from the Ministry of Science and Technology (Mincyt). And within Mincyt, its Agency for the promotion of innovation, research and development, which manages state funds to promote I+D has shown a keen interest in the medical field.

Background

Healthcare expenditures in Argentina account for approximately 9% of the GDP, among the highest in the Latin America region.
Demand can be analysed in two components: the final consumer and the Argentine health system.
Regarding the first, Argentina has a population of 44.7 million with a demography that varies notably depending on the province. In the Province of Buenos Aires, the largest province, demographics are very similar to European countries, with an increasingly aged population and life expectancy. It is noteworthy that the population over 65 years has grown by one million people in the last ten years, which constitutes an opportunity for the sector.

[1] OEC Observatory of Economic Complexity

The Argentine health system is based on the fact that each inhabitant has the right to access the public health service, independently of whether he/she enjoys additional coverage. In 2018, 36.39% of the population was covered by a Social Work institution (called Obras Sociales, related to trade unions) , both national and provincial; 11.62% was covered by PAMI (a public service for the elderly receiving a pension); 13.34% had a private or prepaid plan (health insurance companies known as "Prepagas") and 35.82% was served only through the public health service.

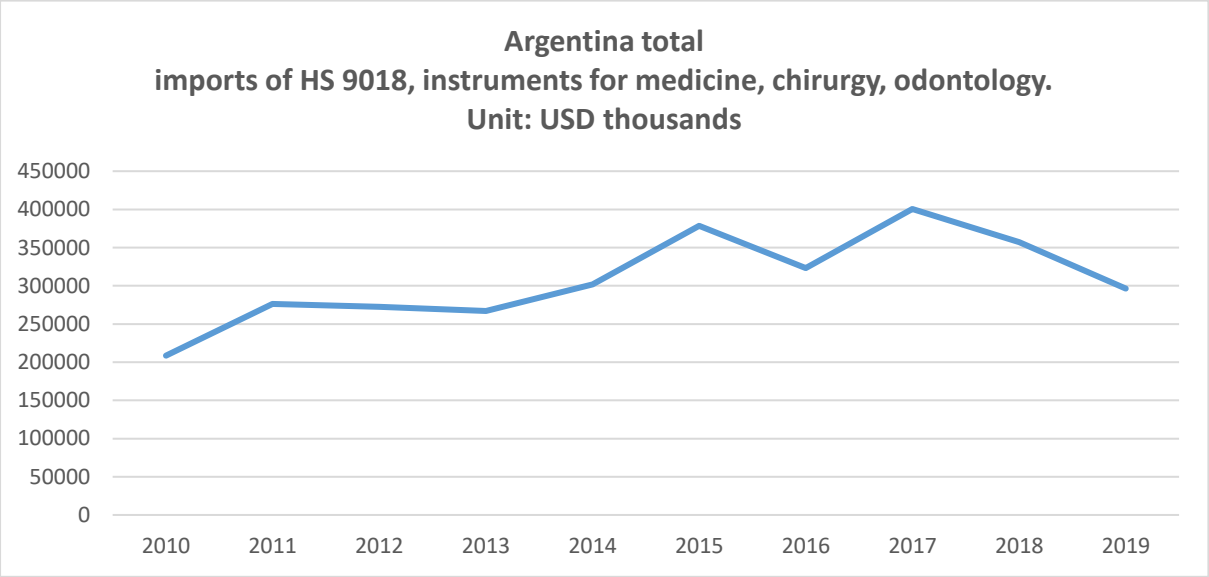
In relation to spending, according to the latest data published, Argentines spent USD 50,151 million on health (USD 1,137.51 per capita).

Imports in the medical equipment and device sector have been estimated of around 70-75% of the total market, with local manufacturing representing the remaining 25%. The total import market amounted to approximately USD 840 million in 2017. Imports have grown almost steadily representing 70% of the total market in 2010 and reaching 82% in 2017. Argentine exports of medical products amounted to USD 57 million in 2017, in a decreasing trend.[2]

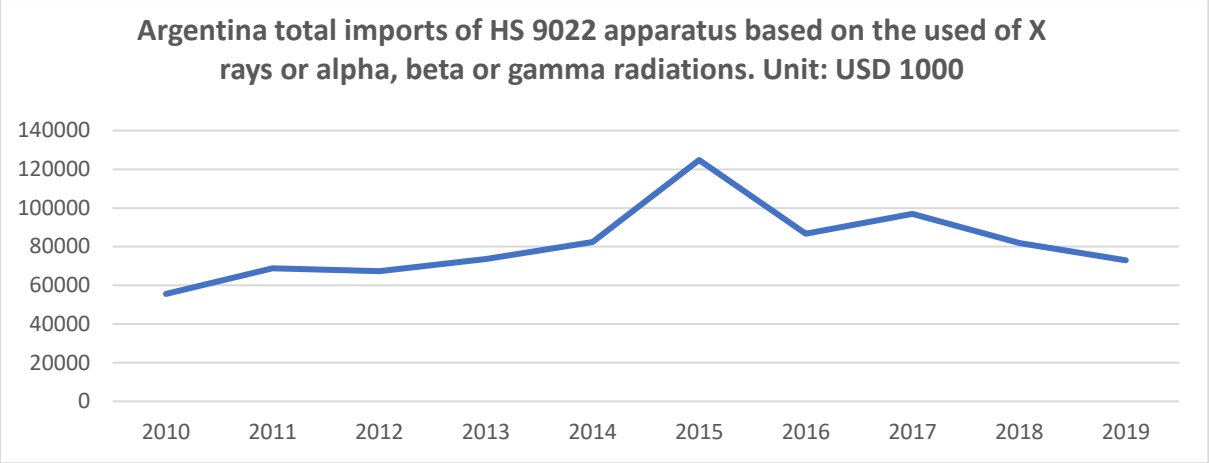
The United States is the leading foreign supplier of imported medical products, with 25% of the import market, followed by China, Germany, Mexico, and Japan. Most imports are concentrated on equipment (50%), followed by implants (29%) and inputs.

The following graphs show the evolution of imports of two example products: medical devices in the HS 9018 position and those of HS 9022.

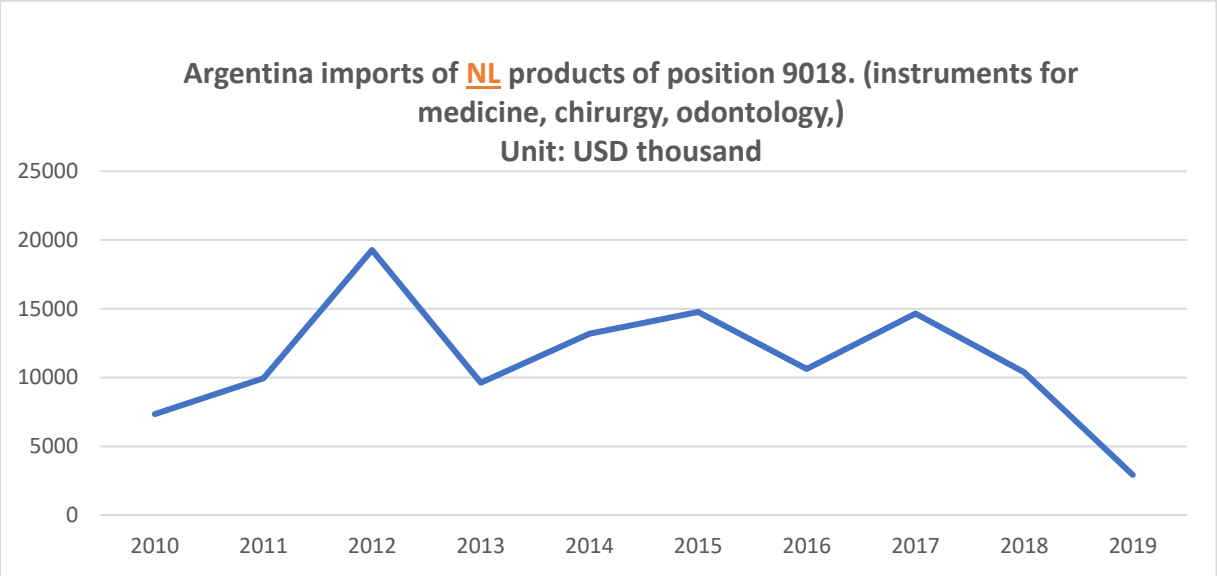
Argentina's total imports from abroad



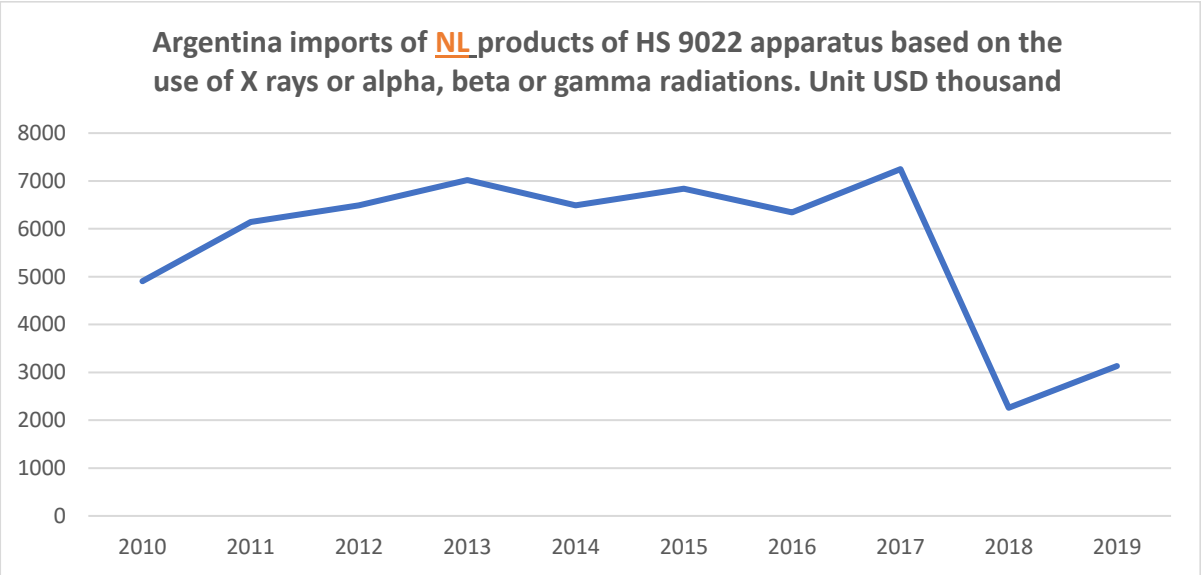
[2] Statistics were based on following Mercosur HS Codes: 90.18.1; 90.18.20; 90.18.3; 90.18.4; 90.18.50; 90.18.90; 90.19.20; 90.21; 90.22.10; 90.22.2; 90.22.30.00; 90.22.90; 90.27.90.99.100.N; 90.27.90.99.200.U.; 30.06.10; 39.2690; 40.1511. Source: CADIEM



Argentina´s **imports from The Netherlands:**



/



The Market access requirements for these products are described below in the Market access section.

Opportunities for collaboration, biotechnology

Argentina's medical technology sector seems adequate to engage with Dutch providers of medical technology. On the demand side, there is a well endowed private medical technology sector, in the form of health insurance companies (known locally as "prepagas")and the hospital structure related to them. On the technical and manufacturing sector, medicine knowledge is built upon a solid academic structure that historically has produced 3 Nobel prizes in the life sciences. The local scientific and technological sector related with lifesciences is well connected with research centers worldwide and atuned to world trends.

An example of the strengths of the biomedical sector in Argentina is the recent bid that the Agency for innovation opened for Covid related projects: Over 900 projects were presented, and 64 were approved. The country is one of the few in the developing world with capacities to develop its own kit for the identification of the virus and also for the manufacturing of respirator devices.
The country is one of the 8 with capacities to develop its own kit for Covid19 testing. Local enterprises Tecme and Leistung represent 2 of the 5 ventilator manufacturers in Latin America, and high tech firm INVAP supplied the technology of a nuclear reactor for medicine research to The Netherlands. Incubators such as CITES located in Santa Fe province specialize in promoting biotech companies.

The Argentine medical technology sector is closely related with the country's strong pharma sector[3] and the biotechnology development industry (that includes agribusiness products). An example of this sinergy is the locally based Grupo Insud.

Argentina posseses important conditions for the further development of the health value chain, such as the availability of medical technology research institutions and interest in technological application and innovation. This seems to provide opportunities for Dutch companies in the health value chain to provide products and services in the area of devices, software and biotechnology, (B2B) and for NL knowledge institutions to exchange scientific research and know how (K2K).

Biotechnology for human health.

There are 201 biotechnology companies in Argentina[4], which places it among the twenty countries with the largest number of companies worldwide, and second in Latin America after Brazil.

These companies work in different activities, among which stand out Human Health (medicines and assisted fertilization) with 32% of the total; biotechnology companies in Argentina collectively bill about USD 15,000 million (year 2014) and USD 2,136 million in exclusively biotechnological products. Human Health represents 13% of the total. Investment in R&D activities reaches USD 91 million, of which Human Health represents 20%.

Although Agro is the sector with the highest spending on R&D, Human Health has a higher level of intensity, allocating around 7 USD out of every 100 of its sales to R&D (versus 4 every 100 in agro).

[3] There are 210 laboratories and 190 manufacturing plants, of which 160 are of Argentine capital and 30 of multinational capital. Also, there are 40 public laboratories that produce medicines. In 2018 the sector exported approx. USD500 million and imported USD720 million. Total sales of the sector amounted to USD 5.902 m.
[4] Ministry of Production of Argentina, March 2019, Sector Report n°2 Biotechnology

In the country there are about 90 scientific institutions and centers that carry out biotechnology R&D activities. The Autonomous City of Buenos Aires concentrates 43% of these institutions, and the remaining ones are located in the provinces as follows: Buenos Aires 24%, Tucumán 9%, Córdoba 7%, Santa Fe 6% and Mendoza 3%[5].

Foreign trade of biotech products. In the area of human health, biotech exports and imports are practically balanced.

The main destinations of the country's exports are in the Latin American region. Sales to South American countries represent about 55% of the total.

The main origins of total biotechnology imports, (not just for human health), are the United States (27%), Switzerland (15%), Germany (15%) and the United Kingdom (12%) and this corresponds to the countries of origin of the main multinational companies present in the sector in Argentina. During the last three years, an annual average of USD 389 million were imported.

Market Access requirements[6]

Applied tariffs and other import duties:

For most position groups related with medical equipment the custom tariffs percentages vary between 0 and 16% of the CIF value. Additional taxes such as VAT also vary, as they are either 21% or 10.5% depending on the position. A statistical tax of 0.5% of the CIF value is charged for some of the positions.

In all cases the importer is charged also a Proportional tax on Profit, levied at a rate of 6% of the duty paid value unless the firm imports the products for its own use as industrial products (not for resale).

For a more specific view, most products within the 9018 category can be imported with 0% MFN tariff. However some positions require a higher tariff: Examples are position 9018.39.30, Lancets for vaccination and cauterising, requiere a 16% tariff; Dental drill engines, whether or not combined on a single base with other dental equipment carry a MFN tariff of between 14 and 16%, as well as certain scalpels (16%) , and Diathermy apparatus (16%).
Similarly most positions in the 9022 group require no MFN duty. However some instruments such as 9022.14.1 (devices for mammography) require a 14% MFN duty.

Additional Duties to be paid are for positions 9018 and 9022 are:

-Value added tax, levied at a rate of 10.5% of the duty paid value.
-Statistical fee (STF):Goods falling under this subheading are exempted from statistical fee.
-Proportional tax on profit is levied at a rate of 6% of the duty paid value. Goods imported for personal use and consumption of the importer are taxed at a rate of 11% of the duty paid

[5] Including the National Institute of Industrial Technology, INTI biotechnology a
[6] The information on market access requirement is primarily sourced from the Market Access Database of the European Commission's website, in June 2020.

value, whilst goods imported as industrial goods for use in the importing company are exempted from proportional tax on profit.

Import Procedures specific for this group of products

Import licences

There are two types of import licenses:

- Automatic: (approved within 24/48hs)
- Non Automatic: (requires special authorization, in some cases explanation on the necessity of the import, among other requirements). This authorization can take up to 60 days.

Most of the positions in groups 9011, 9012, 9019, 9022 and 9027 enter the country through an Automatic Import Licence , usually a brief procedure. Application for the License is to be submitted electronically via the Integrated Import Monitoring System (SIMI) www.afip.gob.ar/simi/ . The period of validity of the import licence is 180 days from the date of approval in SIMI.

Imports of medical products must be performed by an importer registered with ANMAT. (Administración Nacional de Medicamentos, Alimentos y Tecnología Médica), as a frequent importer of medical equipment. Imported products generally appear under the name of the local registered importer who will fulfill the registration process as a representative of the foreign company.

- Registration of Importers of Medical Products

A document certifying that an importer of medical goods is registered with the National Administration of Drugs, Food and Medical Technology, ANMAT.

The registration is a prerequisite for the Registration of Medical Products and for the Import Permit for Medicines, Medical Products, Certain Medical Devices and Cosmetic Products. It is required for customs clearance and market access.

Spanish name of the document = Autorización de Funcionamiento de Empresa Importadora de Productos Médicos

The registration is to be applied for by the importer at the National Administration of Drugs, Food and Medical Technology = Administración Nacional de Medicamentos, Alimentos y Tecnología Médica, ANMAT.

The application is to be completed in Spanish. To be submitted in triplicate.

The processing time is stipulated by the authority. The processing fee varies according to the class the medical product belongs to. The period of validity is stipulated by the authority.

Please note: Diverging application forms are to be completed for the registration of importers of class II, III, IV medical products. The classification of the goods to be imported is based on the respective rules provided for in Annex II of Disposition 2318/02.

- Registration of Medical Products

A document certifying that medical goods have been registered with the National Administration of Drugs, Food and Medical Technology (ANMAT).

The registration is a prerequisite for the Import Permit for Medicines, Medical Products, Certain Medical Devices and Cosmetic Products.

It is required for customs clearance and market access. Spanish name of the document = Registro de Producto Médico.

The registration is to be applied for by the importer at the ANMAT. The application is to be completed in Spanish. To be submitted in the original.

The processing time is 180 days. The processing fee varies according to the class the medical product belongs to. The period of validity is stipulated by the authority.

The ANMAT differentiates between importations of medical goods from recognised and non-recognised countries. The first are countries maintaining a high level and frequency of sanitary controls. These countries include the Member States of the European Union (EU) who have adopted Directives 90/385/CEE, 93/42/CEE and 98/79/CEE and will adopt those which may replace these in the future.

- Import Permit for Medicines, Medical Products, Certain Medical Devices and Cosmetic Products

A document permitting the actual importation of medicines, medical products, in vitro diagnostic devices and cosmetic products.

Required for customs clearance. Spanish name of the document = Autorización para la Importación de Medicamentos, Productos Cosméticos, de Higiene Personal y Perfumes, Reactivos de Diagnóstico de Uso in Vitro y Productos Medicos

The permit is to be applied for by the importer at the National Administration of Drugs, Food and Medical Technology, Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT).

The application is to be completed in Spanish. To be submitted electronically via the platform Procedures at a Distance (Trámites a Distancia - TAD)[7].

[7] In order to obtain access to the TAD, a user account must first be created at https://tramitesadistancia.gob.ar. As a prerequisite, a Tax Payer Registration Code (CUIT) and a fiscal code (of security level two or three) are required. The latter is to be obtained on the website of the Federal Administration of Public Revenue (AFIP).

The processing time is 24 hours in case of cosmetics, products for personal hygiene, perfumes and medicines that are to be cooled, 48 hours in case of all other concerned products. The processing fee varies depending on the value of the importation.

- Certificate of Analysis

A document certifying that microbiological and physical/chemical tests have been carried out by an appropriate laboratory in the country of export.

The document is a prerequisite for the Import Permit for Reproductive Material and the Notification of Arrival for Animal Products and By-Products as well as for the Registration of Dental Hygiene Products and the Import Permit for Medicines, Medical Products, Certain Medical Devices and Cosmetic Products (in case of primary substances), respectively.

It may also be required for the customs clearance and market access of other types of goods or if specifically requested by the importer or for other reasons.

Spanish name of the document = Certificado de Análisis. The Argentine authorities accept certificates issued by an appropriate and duly accredited laboratory in the country of export if all the information required is provided.

The certificate is to be prepared in Spanish or in English. No specific form required

- Free Sale Certificate

A document confirming that the goods in question are freely sold in the country of export.

The document is usually a prerequisite for the registration of foodstuffs, medical and cosmetic products and household cleaning products. Spanish name of the document = Certificado de Libre Venta.

In general, the certificate is issued by an appropriate authority or another institution in the country of export, e.g. by the chamber of commerce. A legalisation may be required, e.g. in case of the registration of cosmetic products.

The Free Sale Certificate may be prepared in any language. However, a translation into Spanish may be requested. It is to be submitted electronically via the platform Procedures at a Distance (Trámites a Distancia – TAD, see previous reference Note).

- Certificate of Good Manufacturing Practice

A document certifying that a manufacturing site of certain pharmaceutical products to be imported and its manufacturing methods comply with the requirements of good manufacturing practice (GMP). It is required for customs clearance and market access.

Spanish name of the document = Certificado de Buenas Prácticas de Manufactura

The competent authority for pharmaceuticals is the National Administration of Drugs, Food and Medical Technology = Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT).

The certificate is to be issued by a competent authority in the country of export. No specific form required. The certificate is to contain the details shown in the model below. The certificate may be prepared in any language. However, a translation into Spanish is recommendable.

A sample of a Certificate of Good Manufacturing Practice recommended by the World Health Organization (WHO) is accepted in Spanish-speaking countries.

Further description of ANMAT regulations on medical products can be found at: www.anmat.gov.ar and also by a simple registration at the EU platform Market Access Database (MADB), http://madb.europa.eu/ in its section on Procedures and Formalities, searching for Argentina and the tariff code.

When consulted to enquire if the registration of simple hospital equipment such as pillows or curtains is necessary ANMAT responded that that there are cases of gray areas, where there is no easy classification of an item as medical or non-medical product. In such cases they recommend that a Consulting File ("Expediente de Consulta") be presented to ANMAT's Direction of Medical Products by the prospective importer with all the documentation available. The ANMAT will respond in 1 or 2 months on whether registration with them is needed.

Institutions that regulate the sector

• Administración Nacional de Medicamentos, Alimentos y Tecnología Médica, ANMAT: National Administration of Medicines, Food and Medical Technology (Avenida de Mayo 869, AR-C1084AAD Buenos Aires, phone numbers: +54 11 43400800, 43428684):

Under the Ministry of Health and Social Development, it was created in 1992 to regulate medicines, food products, diagnostic reagents, cosmetic products, dietary supplements, and household cleaning products. Intervenes in the process of authorization, registration, standardization, surveillance and monitoring of products.

• Comisión Nacional Asesora para la Conservación y Utilización Sostenible de la Diversidad Biológica National Advisory Commission for the Conservation and Sustainable Use of Biological Diversity, CONADIBIO: it was created in 1997 from the regulation of National Law No. 24,375, which approves the Convention on Biological Diversity (CBD), in charge of the then Secretariat of Environment and Sustainable Development.dependiente del Ministerio de Salud y Desarrollo Social, fue creada en 1992 para regular medicamentos, productos alimenticios, reactivos de diagnóstico, productos cosméticos, suplementos dietéticos y productos de limpieza para el hogar. Interviene en el proceso de autorización, registro, estandarización, vigilancia y monitoreo de los productos.

Sector events

- Expomedical-"International show for products, services, and equipment"
  When: September 23-25, 2020, Buenos Aires
  Webpage: www.expomedical.com.ar

- ETIF-“Congress and exhibition for pharmaceutical, biotechnological, veterinarian and cosmetic science and technology”
  When: April 7-9, 2021 , Buenos Aires
  Webpage: https://www.etif.com.ar/en/

Links of interest

- ANMAT, medical products
- CADIEM – Chamber of Importers and Manufacturers of Medical Equipment
- CAEHFA - Chamber of Manufacturers of Hospital Equipment in Argentina
- Pan American Health Organization - Representation in Argentina
- Association of Institutions of Medical Diagnosis (CADIME)
- Argentine Association of Healthcare Centers (CAES)
- Argentine Ministry of Health/ Healthcare Plans
- CIRA Chamber of Importers of Argentina

This is a publication of
Netherlands Enterprise Agency
Prinses Beatrixlaan 2
PO Box 93144 | 2509 AC The Hague
T +31 (0) 88 042 42 42
E klantcontact@rvo.nl
www.rvo.nl

This publication was commissioned by the ministry of Foreign Affairs.

© Netherlands Enterprise Agency | July 2020
Publication number: RVO-120-2020/RP-INT

NL Enterprise Agency is a department of the Dutch ministry of Economic Affairs and Climate Policy that implements government policy for Agricultural, sustainability, innovation, and international business and cooperation. NL Enterprise Agency is the contact point for businesses, educational institutions and government bodies for information and advice, financing, networking and regulatory matters.

Netherlands Enterprise Agency is part of the ministry of Economic Affairs and Climate Policy.