INFOCARD ELANBiz

Medical Devices: Market access requirements in Peru[1]

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The purpose of this infocard is to provide information on the main aspects to consider for the import of medical devices in Peru.

Introduction

Peru is among the Latin American markets with the greatest potential for the medical industry[2]. While it is true that Peru allocated only 5% of its GDP to public spending on health in 2017, which is below the 8.2% Latin American average[3], this insufficiency represents investment opportunities for those engaged in importing and marketing medical devices. In 2019, Peru imported a total of USD 368 million of medical equipment and devices, which represents an increase of 8% compared to 2018[4]. In addition, various projects for the construction, improvement and remodeling of hospitals have been adopted under the framework of GtoG agreements with the United Kingdom and France; alongside investments in the health industry amounting to PEN 20 billion, which will result in a greater demand for these products[5].

Likewise, the Congress has declared of public necessity and national interest the increase of the health budget to 8% of GDP within a progressive period of 3 years[6]. In that regard, in his speech of 28 July 2020, former President Vizcarra announced the execution of investment projects in the health sector of up to PEN 30 billion: PEN 7 billion in the execution of different public works (Authority for Reconstruction with changes), including 15 health facilities; PEN 3 billion in the construction of 44 hospitals and health centers, under the GtoG Agreement contracting scheme; and PEN 20 billion in improving the quality of health services, through the execution of the General Budget of the Republic for the year 2021[7].

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[1] *The information provided in this document is of a general nature only. For more detailed information, events and commercial trade offers as well as commercial business contacts, please contact the Commercial Offices of the Member States and the bilateral chambers of commerce in Lima.*

[2] https://www.diagnosticsnews.com/noticias/33460-dispositivos-medicos-el-potencial-mercado-peruano-de-los-dispositivos-medicos

[3] EY – Peru Oxford Business, Covid-19 Response Report, August 2020.

[4] Source: Trade Map. Partidas 9018, 9019, 9020, 9021, 9022 y 9402.

[5] https://comunicaciones.congreso.gob.pe/noticias/anuncian-20-mil-millones-de-soles-en-el-presupuesto-del-sector-salud-para-el-2021/

[6] Draft of Investment Report. Technical support to the market access and analysis of comercial policies team of the EU in Peru. MATPeru. Last updated 14 August 2020.

[7] For regimes applicable to Public Tenders and GtoG agreements, concerning the purchase of medical devices, please check the Public Procurements infocard.
https://www.elanbiz.org/documents/20182/56601/Public+Procurement+in+Peru/84921c0b-f86d-47e3-92c9-03bf28dca4ef

Nomenclature

The national legislation establishes that **Medical Devices** include any instrument, device, implement, machine, reagent or in vitro calibrator, computer application, material or other similar or related article, intended by the manufacturer to be used in human beings, alone or in combination, for one or more of the following specific purposes:[8]

- Diagnosis, prevention, monitoring, treatment or alleviation of a disease.
- Diagnosis, monitoring, treatment or alleviation of or compensation for an injury.
- Investigation, replacement, modification or support of human anatomy or of a physiological process.
- Support or maintenance of life.
- Birth control.
- Disinfection of medical devices.

Following the Common Nomenclature of the Andean Community countries (NANDINA), the subheadings that have been considered for each group of products in this infocard are the following:

CODE	DESCRIPTION
90.18	Instruments and devices for medicine, surgery, dentistry or veterinary medicine, including those for scintigraphy and other electromedical devices, as well as devices for visual tests. Electrodiagnostic devices (including devices for functional examination or for monitoring physiological parameters).
90.19	Mechanotherapy devices; massage devices; psychotechnics devices; ozone therapy, oxygen therapy or aerosol therapy devices, respiratory resuscitation devices and other respiratory therapy devices.
90.20	Other respiratory devices and gas masks, except protective masks without a mechanism or removable filter element.
90.21	Orthopedic supplies and appliances, including surgical girdles and bandages, as well as crutches; splints or other items and appliances for fractures; prosthetic articles and appliances; hearing aids and other devices with the prosthesis. Joint prostheses as well as other articles and orthopedic devices used for fractures.

[8] Article 3° of Law N° 29459 – Law on pharmaceutical products, medical devices and sanitary products.

CODE	DESCRIPTION
90.22	X-ray devices and devices that use alpha, beta or gamma radiation, including for medical, surgical, dental or veterinary use, including radiography or radiation therapy devices, X-ray tubes, and other generating devices. X-ray devices, including for medical, surgical, dental or veterinary use, radiography or radiotherapy units.
94.02	Furniture for medicine, surgery, dentistry or veterinary medicine (for example: operating or examination tables, beds with mechanisms for clinical use, dental chairs); hairdressing chairs and similar, with devices.

Source: Sunat, as of November 2020

Trade Agreement between Peru and the EU

The Multiparty Trade Agreement between the EU, Colombia, Ecuador and Peru (the "**Agreement**") has allowed to exempt most medical devices of European origin from paying tariffs in Peru. To benefit from that exemption, the importer of **products originating in the EU** must present the **EUR 1 certificate** duly obtained by the exporter in the Member State of origin, as an evidence of the origin of the product.

Unless otherwise established in the Tariff Elimination Schedule of Peru, the following staging categories apply to the elimination of customs duties in Peru, in accordance with paragraph 1 of Article 22° (Elimination of Customs Duties) of Title III (Trade in Goods) of the **Agreement**:

- ✓ Tariff subheadings belonging to category "0" will be completely eliminated and will be duty-free as of the entry into force of the **Agreement**.
- ✓ Category subheadings belonging to category "10" will be eliminated in eleven stages, in equal proportions, beginning from the entry into force of the **Agreement** and will be duty-free by 1 January of year eleven.

TARIFFS APPLICABLE TO IMPORT OF MEDICAL DEVICES ORIGINATING FROM EU MEMBER STATES

Code	Description	Base Rate	Category	Ad Valorem 2020
90.18	Instruments and devices for medicine, surgery, dentistry or veterinary medicine, including those for scintigraphy and other electromedical devices, as well as devices for visual tests. Electrodiagnostic devices (including devices for functional examination or for monitoring physiological parameters).	0	0	0%

Code	Description	Base Rate	Category	Ad Valorem 2020
90.19	Mechanotherapy devices; massage devices; psychotechnics devices; ozone therapy, oxygen therapy or aerosol therapy devices, respiratory resuscitation devices and other respiratory therapy devices.	0	0	0%
90.20	Other respiratory devices and gas masks, except protective masks without a mechanism or removable filter element.	0	0	0%
90.21	Orthopedic supplies and appliances, including surgical girdles and bandages, as well as crutches; splints or other items and appliances for fractures; prosthetic articles and appliances; hearing aids and other devices with the prosthesis. Joint prostheses as well as other articles and orthopedic devices used for fractures.	9	0 - 10	0 - 6%
90.22	X-ray devices and devices that use alpha, beta or gamma radiation, including for medical, surgical, dental or veterinary use, including radiography or radiation therapy devices, X-ray tubes, and other generating devices. X-ray devices, including for medical, surgical, dental or veterinary use, radiography or radiotherapy units.	0	0	0%
94.02	Furniture for medicine, surgery, dentistry or veterinary medicine (for example: operating or examination tables, beds with mechanisms for clinical use, dental chairs); hairdressing chairs and similar, with devices.	0	0	0%

Source: Aduanet (Sunat), as of November 2020

Import Procedure

The **manufacture, import, storage, distribution, marketing, promotion, advertising, prescription, pharmaceutical care, sale, use and final destination of medical devices** in Peru, is regulated by the **General Directorate of Medicines, Supplies and Drugs - DIGEMID**[9]. This institution is responsible for granting the corresponding Sanitary Registry that authorizes the importation of medical devices into the country[10].

Medical devices are listed as **restricted goods**, and as such, they are subject to a **differentiated**

[9] Article 2° of Law N° 29459 – Law on pharmaceutical products, medical devices and sanitary products.
[10] Article 8° of Law N° 29459 – Law on pharmaceutical products, medical devices and sanitary products.

treatment. Indeed, in addition to the relevant customs documentation, their import is conditional on obtaining an authorization issued by **DIGEMID**. In order to apply for such auhtorization the importer must register before **DIGEMID** as a Drug Store or Laboratory, following the steps below:

N°	DRUG STORE	LABORATORY
01	Incorporate the business and obtain a Tax Registry (*RUC*).	Incorporate a company and register, both the legal and natural persons, with SUNARP, SUNAT and the corresponding Municipality.
02	Hire the services of a professional pharmaceutical chemist (specialist in regulatory issues), who shall take the position of technical director of the drugstore.	Hire the services of three pharmaceutical chemical professionals, to assume the positions of: ❖ Technical Director and Head of Quality Assurance ❖ Production Manager ❖ Head of Quality Control
03	Have an establishment with an administrative area and a warehouse area.	Have an establishment with a management office, a manufacturing plant and a warehouse, in accordance with the Good Manufacturing Practices Manual.
04	Start the application for the Registry of the establishment through form A-2 (www.digemid.minsa.gob.pe/Main.asp?Seccion=624) submitting all the requirements and application fee of **PEN 478.40**, paid at the Peruvian National Bank (*Banco de la Nación*), under code 6556.	Start the application for the Registry of the establishment through form A-2 (www.digemid.minsa.gob.pe/Main.asp?Seccion=624) submitting all the requirements and application fee of **PEN 891.80**, paid at the Peruvian National Bank (*Banco de la Nación*), under code 6556.
• The documents will be submitted through the entity's Application Desk (Av. Parque de las Leyendas n°246 – San Miguel – Lima; between the hours of: 8:30 am to 4:30 pm). • The process is subject to prior inspection and the evaluation time, according to the Text of Administrative Procedures, is 30 business days. • Once registered as a Drugstore, the pharmaceutical establishment can start activities and the pharmaceutical chemist can manage the Health Registries of the products he wishes to import.		• The documents will be submitted through the entity's Application Desk (Av. Parque de las Leyendas n°246 – San Miguel – Lima; between the hours of: 8:30 am to 4:30 pm). • The process is subject to prior inspection and the evaluation time, according to the Text of Administrative Procedures, is 30 business days.

However, it should be noted that current regulations do not authorize doctors, health professionals or medical students to import medical devices intended for personal use or the exercise of their profession[11]. Likewise, the only procedure that allows a natural person to import a medical device is

[11] Answer N° 02: http://www.digemid.minsa.gob.pe/Main.asp?Seccion=852#cuatro

through a medical prescription as long as the equipment is intended for individual treatment. This procedure is called **Exceptional Import Authorization**: it is subject to a "Validation of the Prescription" and is only intended for preventive care, individual treatments and emergency cases[12].
This procedure requires a medical prescription or justification issued by a health professional within the national territory, which must include the **minimum prescription requirements**[13] and a report with the characteristics of the product or medical device containing at least the following information: use intended by the manufacturer, operation of the device, technical specifications of the product.

Market Access Requirements

The requirements for medical equipment from European Union countries to access the Peruvian market include the general sales tax, sanitary registration and other specific import requirements for these products.

1. General sales tax

Imported merchandise is subject to the payment of the **General Sales Tax (*IGV*)**, at a rate of **16%**, and the **Municipal Promotion Tax (*IPM*)**, at a rate of **2%**. It should be noted that for both of them, **the tax base is made up of the Customs Value plus customs duties and other taxes that affect imports**.

2. Sanitary Requisites

2.1 Import of medical devices ("Technical Inquiry")

In order to allow the entry of a medical device, Customs requires either the authorization of DIGEMID (Sanitary Registry) or, if not applicable, a document issued by DIGEMID stating that the device does not require authorization, given that such product, due to its nature, characteristics, performance and use is not subject to registry in accordance with current health regulations[14]. In this regard, the interested party must submit to DIGEMID a Technical Inquiry in order to corroborate whether it is necessary to apply for a Sanitary Registry.

Technical Inquiry - Sanitary Registry requirement (Request for authorization or document stating that the product does not require Sanitary Registration). Inquiries for the Sanitary Registration requirement can be made by two means:

a. Physical letter, addressed to the General Director of DIGEMID, with the sender's data (names,

[12] Art. 16 of Law N° 29459 – Law on pharmaceutical products, medical devices and sanitary products and Article 20° of Supreme Decree N° 016-2011-SA – Rules of Procedure for the Registry, Control and Sanitary Oversight of Pharmaceutical Products, Medical Devices and Sanitary Products.
[13] Article 56° of Supreme Decree N° 014-2011-SA – Rules of Procedure for Pharmaceutical Establishments. When a medical device is prescribed, aside from sub-sections a), b), i) and j), the prescription should contain the name or denomination of the medical device. Additionally, the brand, model, code and other specific characteristics, wherever applicable.
[14] See paragraph 2.5 of Sanitary Requisites.

DNI, address, telephone) in writing, whose subject should read "Technical Inquiry - Sanitary Registry requirement".

- ❖ Detail the characteristics of the product (name, purpose, mode of use, brand, model, form of presentation, technical specifications, label, etc.)
- ❖ The sender or, in the case of a company, the Legal Representative must sign, indicating company name, Tax Registry (*RUC*), address and telephone number.
- ❖ Documents shall be submitted at Av. Parque de las Leyendas N° 246 – San Miguel – Lima; between the hours of 8:30 am to 4:30 pm.

b. By means of the following link. At the end you will be assigned an inquiry number and a password that will be used to access the response issued by the entity. In both cases, the estimated time for the process is 30 business days. If the answer is positive, you must apply for a Sanitary Registry with DIGEMID.

2.2. Applying for a sanitary registry with DIGEMID

To apply for a Sanitary Registry or request a change in a previously granted Sanitary Registry of Medical Devices, you must follow the steps below:

a. Obtain a Sanitary Authorization for Operating a Drugstore or Laboratory (Article 2° of Supreme Decree N° 014-2011-SA) correspondingly, or be Registered as such in the National Information System - Pharmaceutical Establishments Module.

b. Identify the Item corresponding to the procedure to be carried out, check the requirements, application fees, deadlines, evaluation of the procedure, authority in charge of the procedure, in order to carry out correctly the formality[15].

c. Identify the form corresponding to the type of procedure you wish to carry out, correctly enter all the requested information, print in two sets and attach all the remaining requirements, including the receipt of payment made at the Peruvian National Bank, and submit two sets before DIGEMID; through the Single Window for Foreign Trade (VUCE).

2.3 VUCE Application

The application for registry of medical devices can be submitted through the Single Window for Foreign Trade[16]. In order to submit the application, please follow the steps listed below:

[15] Tex of Administrative Procedures of DIGEMID – Procedures 246 through 255.
[16] Ibid.

STEP 1

Visit https://www.vuce.gob.pe/

Login

STEP 2

LOGIN WITH "SOL" PASSWORD:
The applicant (Exporter, Importer, Customs Agent or Laboratory) must login with their Tax Registry (*RUC*), SOL password (SUNAT Online Operations), as well as the USER and KEY codes granted to them when creating a Secondary User to Access the VUCE.

STEP 3

PAYMENT OF THE FEE:
Once the secondary User has been created, this option allows the creation of a Single Foreign Trade Request (SUCE), but in order to transmit it to the Entity, the corresponding fee must be paid.

Application

STEP 4

CREATING AN APPLICATION:
There are two ways to select the TUPA / Relevant Application Form, one of these is by clicking on the "NEW APPLICATION" button; the other is to choose the TUPA / Form, and selecting the corresponding Entity from the drop-down list.

STEP 5

FILLING THE APPLICATION:
Fill in the application data as required by the SUCE, and submit the application.

Resolution

STEP 6

RESOLUTION:
Once submitted, the corresponding Entity will review the documents and issue the corresponding response.

2.4 Labeling

Medical devices must comply with the following general aspects regarding the labeling of the outer and inner containers of the device:[17]

a) The information on the labeling of the outer and inner containers, as well as on the instructions for the use of medical devices, must be written in Spanish with indelible, easy to read and visible characters. Additionally, they can appear in other languages, in addition to Spanish, as long as that information corresponds to the one contained in the sanitary registry of the medical device;

b) All medical devices must include instructions for use on their packaging. Exceptionally, these instructions may not be included on the packaging of Class I[18] medical devices as long as their safe use can be guaranteed without the aid of such instructions. When the instructions for use are indicated in the manual or attachment, including them on the packaging will be optional, as as long as the latter indicates "see manual or attachment" or similar;

c) The information necessary for the use of medical devices must be written, whenever feasible and appropriate, on the medical device itself and/or on its outer and inner packaging;

d) Instructions for use must be written in terms easy to understand for the user;

e) If there is a need for additional information due to the specificity of medical devices, it must be added into the labeling or in the instructions for use, wherever applicable.

f) The use of international symbols, described and defined in Annex Nº 04 of the Rules of Procedure of Law N° 29459, is allowed in the labeling of medical devices.

g) In the labels whose information is written in languages other than Spanish, a simple Spanish translation of the instructions (intended purpose) and precautions must be added;

h) For medical devices manufactured in the country all the labeling must be in Spanish, although more languages may be added if the manufacturer wishes so;

i) Biomedical equipment and biomedical equipment with controlled technology are exempt from labeling. The sterile accessories that accompany the biomedical equipment and biomedical equipment with controlled technology must be labeled according to the

[17] Article 137° of Supreme Decree N° 016-2011-SA – Rules of Procedure for the Registry, Control and Sanitary Oversight of Pharmaceutical Products, Medical Devices and Sanitary Products.
[18] Medical devices are classified according to their level of risk. See the section for **Market Access Difficulties** of this infocard.

corresponding specific labeling requisites.

2.5 Products which do not require sanitary registry

DIGEMID publishes on its website the list of products which do not require sanitary registry to be marketed in Peru, whether they are of local manufacture or foreign origin. In total, 1,095 products, due to their nature, characteristics, performance and use do not require registry in accordance with current health regulations. The list contains the name of the products and the description of each one of them, in order to facilitate their identification by the user.

If the product is not contained in the list, the interested party has to submit a Technical Inquiry.

2.6. Special Authorization for Medical Devices for In Vitro COVID Diagnosis:

In order to fight the spread of COVID-19, DIGEMID has created a special authorization for medical devices for in vitro diagnosis, for **(i) the manufacture of devices, exclusively for research purposes** and **(ii) the manufacture and use during an emergency declared by the government**[19].

Market Access Difficulties

In 2017, *Eurocámaras Peru* warned that, despite the Peruvian legislation acknowledging and using the concept of **High Sanitary Surveillance Countries**[20], the application of sanitary registry for medical devices in Peru involved excessive regulations and costs[21]. Indeed, in spite of the apparent simplicity of the procedure, it has been repeatedly found that obtaining a Sanitary Registry may take more than two (02) years, due to delays by DIGEMID, making it one of the longest procedures worldwide[22].

On the other hand, it should be added that Peru does not recognize all the Member States of the European Union as High Sanitary Surveillance Countries, limiting itself only to: France, the Netherlands, Switzerland, Germany, Spain, Denmark, Italy, Norway, Belgium, Sweden, Portugal and Austria[23]. In this regard, Peru still has not adapted its internal legislation to the Trade Agreement signed with the European Union, which would imply the recognition of all Member States.

[19] http://www.digemid.minsa.gob.pe/UpLoad/UpLoaded/PDF/Comunicados/2020/C44_2020-09-16-.pdf

[20] Country which maintains high public health indicators, has universal coverage in health insurance for its population or ensures the provision of social protection services, has low rates of maternal and child mortality, presents development of basic sanitation infrastructure, exercises occupational hygiene and environmental protection, has strengthened health surveillance and oversight systems, as well as a consolidated quality assurance system, among other indicators that place it as a benchmark country in the world in health surveillance; in accordance with numeral 73 of Annex N° 01 of Supreme Decree N° 016-2011-SA – Rules of Procedure for the Registry, Control and Sanitary Oversight of Pharmaceutical Products, Medical Devices and Sanitary Products.

[21] 2017. Eurocámaras Perú. Position Paper – Eurocámaras Perú. Pp 3 – 4.

[22] 2017. Eurocámaras Perú. Position Paper – Eurocámaras Perú. Pp 3 – 4.

[23] Article 9° of Supreme Decree N° 016-2011-SA – Rules of Procedure for the Registry, Control and Sanitary Oversight of Pharmaceutical Products, Medical Devices and Sanitary Products.

Likewise, the commercialization of medical devices is restricted in accordance with their risk classification:[24]

N°	CLASS	SALE
01	**Class I**: low risk	Sale without medical prescription, with exception of contact lenses, which are sold with prescription.
02	**Class II**: moderate risk	
03	**Class III**: high risk	❖ Sale with medical prescription, ❖ Sold exclusively to health professionals and establishments.[25]
04	**Class IV**: critical risk	

In addition, it should be noted that, with the exception of low health risk products, the sale of medical devices can only be carried out by pharmaceutical establishments with the proper Health Authorization of Operation, granted by DIGEMID[26]. For their part, the rules to determine the risk and proper classification of medical devices, are established in Annex 1 of Supreme Decree N° 003-2020-SA – Rules of Procedure which establish the Classification Rules and the Main Principles of Safety, Security and Performance of Medical Devices.

As indicated, it is considered that this type of regulation is excessive, with a special emphasis on obtaining the Sanitary Registry, so that in practice it has become an unjustified barrier for the entry of goods and innovative technology for health in Peru. This motivated *Eurocámaras Peru* to request the adoption of European international standards in the Peruvian legislation, as well as to indicate the need for an automatic or expedited recognition for products with international certification[27].

On 08 November 2017, the European Chamber (*EuroCámaras Perú*) held an event on "European Legislation on Medical Devices", with the purpose of presenting the market access difficulties faced by such products when trying to enter the Peruvian market. The event had the participation of the officials and directors of DIGEMID, and included talks about the necessity of adapting the Peruvian legislation in order to recognize European high standards of manufacture and commercialization of medical devices.[28]

For its part, on 17 September 2020, DIGEMID indicated the validity of a procedure of "**Special Authorization for the Manufacture, Import and Use of Pharmaceutical Products and Medical Devices in Situations of Urgency or Emergency Declared by the Government**" [29]. Thus, DIGEMID set the

[24] Artículo 135° of Supreme Decree N° 016-2011-SA – Rules of Procedure for the Registry, Control and Sanitary Oversight of Pharmaceutical Products, Medical Devices and Sanitary Products.

[25] With the exception of medical products specifically intended for disinfection, cleaning, rinsing or, where appropriate, hydrating contact lenses, which will be registered and sold without prescription.

[26] Article 21° de la Ley N° 29459 – Law on pharmaceutical products, medical devices and sanitary products and Article 2° del Decreto Supremo N° 014-2011-SA – Rules of Procedure of Pharmaceutical Establishments.

[27] 2017. Eurocámaras Perú. Position Paper – Eurocámaras Perú. P – 5.

[28] 2017. Activity Report Business Breakfast. ALUE – EU Public Diplomacy in Latin America.

[29] http://www.digemid.minsa.gob.pe/UpLoad/UpLoaded/PDF/Comunicados/2020/C45_2020-09-18.pdf

following link to submit the application. This application must be submitted using the preapproved Affidavit Form, numbered and scanned in PDF format, as well as a copy of the Emergency Declaration Resolution issued by MINSA and the list of the products or devices with their technical specifications.

In attention to the specific case of medical devices, the pandemic has generated a demand for devices such as protective masks, critical medical equipment, among other supplies. Fierce competition among countries to purchase these goods has shown governments around the world how difficult it can be to rely on global chains to supply themselves adequately. This experience could encourage health authorities and private providers of health services to diversify their sources of supply. Potential EU investors could use this opportunity to search for new clients.[30]

Useful Links

- DIGEMID: General Directorate of Medicines, Supplies and Drugs: http://www.digemid.minsa.gob.pe/
- MINSA: Ministry of Health https://www.gob.pe/minsa/
- Supervisory Authority of Public Procurement https://www.gob.pe/osce
- SUNAT: National Superintendence of Customs and Tax Administration http://www.sunat.gob.pe/
- Single Window for Foreign Trade (E): MANUALS – RESTRICTED GOODS: https://www.vuce.gob.pe/documentacion.html

[30] Ibid. P – 62.

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