

MEDTECH IN PERU

A growing and dynamic market (Part 2)



Official Program Partner

Medtech in Peru
A growing and dynamic market.

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List of Abbreviations

ACP	Association of Private Clinics of Peru
AFOCAT	Association of Regional or Provincial Funds against Traffic Accidents
ADEX	“Asociación De Exportadores”. Leading Peruvian foreign trade business association
B2B	Business to Business
CCSP	Swiss Chamber of Commerce in Peru
CE	European Community
COMEXPERU	Foreign Trade Society of Peru
COMSALUD	Health Association of the Lima Chamber of Commerce
DIGEMID	General Directorate of Medicines, Inputs and Drugs
EFTA	European Free Trade Association
EMA	European Medicines Agency
EPS	Health Provider Companies
ESSALUD	Peruvian Social Health Insurance
FAP	Peruvian Air Force
FDA	U.S. Food and Drug Administration
FFAA	Armed Forces
GDP	Gross Domestic Product
HS	Harmonized System
IAFA	Health Insurance Funds Administration Institution
IAFAS-EP	Peruvian Army Health Insurance Fund Administration Institution
IAFAS-FOSFAP	Health Insurance Fund Administration Institution of the Peruvian Air Force
IAFAS-FOSMAR	Health risk coverage service, insurance plans and respective benefits for Military, Cadets and Students
IMDRF	International Medical Device Regulation Forum
INPE	National Penitentiary Institute
IPEN	Peruvian Institute of Nuclear Energy
IPRESS	Institutions Providing Health Services
ISO	International Organization for Standardization
ITSE	Technical Building Safety Inspection
MINSA	Ministry of Health of Peru
MRE	Ministry of Foreign Affairs
ORL	Otorhinolaryngology
PEAS	EsSalud's Essential Health Insurance Plan
PNP	National Police of Peru
Prepagas	Prepaid Health Services Provider Entity
R&D	Research and Development
RPMV	Public Stock Exchange Registry
RUC	Single Taxpayer Registry
S.A.	Public Limited Company
S.A.A.	Open Joint Stock Company
S.A.C.	Closed Joint Stock Company

S.R.L.	Limited Liability Company
SALUDPOL	Health Insurance Fund of the Peruvian National Police
SIS	Integral Health Insurance
SME	Small and medium-sized enterprise
SMV	Peruvian Securities and Exchange Superintendence
SUNARP	National Superintendence of Public Registries
SUNAT	National Superintendence of Customs and Tax Administration
SUSALUD	National Superintendence of Health
S-GE	Switzerland Global Enterprise
VAT	Value added tax
VUCE	Single Window for Foreign Trade
WHO	World Health Organization
WTO	World Trade Organization

1. FOREWORD

The Swiss Chamber of Commerce in Peru has elaborated this report on Medtech in Peru with the support of Switzerland Global Enterprise (S-GE). The Chamber thereby fosters and promotes the free market system, and encourages trade and investment within a framework of social responsibility, strong values and business ethics.

Aware of the significant needs of Peru for Medtech products, this report seeks to identify business opportunities for Swiss firms addressing the following questions:

- What are the Medtech product categories mostly exported by Switzerland around the world?
- Which Medtech products does the Peruvian industry produce and export?
- What is the importance of Switzerland in Peru's Medtech imports?
- What are the legal regulatory requirements for market authorization?
- How to deal with logistics and distribution?
- What is the potential of the Peruvian market for Swiss Medtech exports and what are the key challenges to succeed?

Swiss and Peruvian trade statistics have been used to analyse the data. Several firms and institutions active in the Peruvian Medtech sector are to be thanked for valuable contributions through a questionnaire, interviews and videos. We are also grateful to Mrs. Andrea Baldeon and Mr. Diego Guevara for undertaking the research, data analysis, elaborating the figures and tables and writing the various chapters.

Special gratitude is expressed to Dr. Philippe G. Nell for designing the project, selecting the main categories of Swiss Medtech exports, writing various parts of the report as well as assuming the overall direction and detailed review of the report.

The Swiss Chamber of Commerce in Peru is confident that this report will increase the awareness of Swiss firms for the Medtech sector in Peru confirming our mission of being the main reference for trade and investment relations between Peru and Switzerland.

We wish you an instructive and pleasant read.

Lima, February 2022

Corinne Schirmer
General Manager
Swiss Chamber of Commerce in Peru

2. EXECUTIVE SUMMARY

The Peruvian health market is highly dynamic and rapidly growing. Needs for a 34 million population are very significant and additional resources constantly allocated to health. The objective of this report is to identify business opportunities for Swiss SMEs in Peru focusing on eight areas accounting for most Swiss exports to the world: i) Dental medicine; ii) Orthopedics; iii) Ophthalmology; iv) In-vitro diagnostics; v) Radiology imaging; vi) Surgical instruments and techniques; vii) Disinfectants and sterilization, and viii) Hearing aids, throat.

Market Overview: Swiss Medtech exports amounted to US\$13.1 billion in 2019 and were mainly directed to Europe (80%); exports to Peru (US\$14.4 million) increased, between 2017 and 2019, by 9.5%, more than overall Swiss exports to the world (+ 6.2%). Peru has only a small number of manufacturers specialized in products with little added value. Most of the medical devices are therefore imported.

In 2019, Medtech imports amounted to US\$589 million mainly from China, the United States and Germany. Between 2015 and 2019, Peruvian imports of Medtech products registered a growth rate of 22%.

In 2019, Switzerland had the largest market share in hearing aids and throat (26%) and orthopedics (19%). Its share was very low for ophthalmology (2%), surgical instruments (1.7%), disinfectants (1.3%), in-vitro-diagnostics (1.1%) and radiology imaging (0.9%).

Regulatory Overview: Requirements referring to registration, market authorization and supervision of medical devices are one of the most difficult aspects to manage and can be very time consuming. The main agency in charge is the General Directorate of Medicines, Inputs and Drugs (DIGEMID).

To seek a sanitary registration with DIGEMID, a Swiss firm can either set up in Peru a company called "Droguería" or request the services of a local company.

Opportunities and challenges: In product groups with strong growth in imports to Peru, Swiss firms are present for reagents, furniture for medical and surgical use, dental fittings, and articles to compensate for a defect. Nine other Swiss products are also among the fastest growing ones. Opportunities are seized by firms. However, positions could be further strengthened over the coming years as the volume of Swiss exports remains modest.

For some products, despite strong growth in imports to Peru, Swiss growth performance has been weak or negative, namely for apparatus based on the use of X-rays, therapeutic respiration apparatus, pacemakers and adhesive dressings. Market opportunities exist for these products as Peru's demand has been increasing robustly.

Swiss firms also register a strong growth for electro-diagnostic apparatus, instruments used in dental sciences and X-ray generators despite the fact that Peru's demand has been growing slowly. This implies that Swiss products are gaining market shares and seizing business opportunities.

Despite strong growth, the Peruvian market raises significant challenges. According to the 2020 World Bank's "Doing Business" report, Peru ranked 133rd for starting a business. Taxes obligations are very time-consuming (rank 121st). Cross-border trade is slow and costly (rank 102nd). According to a company, important hurdles in the Medtech

sector are related to lack of flexibility in procedures and absence of agreements with other regulatory agencies such as those of the United States and the European Union.

The business climate is also strongly affected by the country's unstable political climate, lack of legal security, weak protection of intellectual property, informality and corruption.

Important Market Players: In 2019, more than 3000 companies imported Medtech products in Peru. The three largest importers accounted for US\$54 million. The major competitors of Swiss firms were China, the United States and Germany (US\$305 million). On a product basis, Switzerland ranked in the top 3 for seven Medtech devices imported by Peru and in the top 5 for 14.

Private clinics and hospitals managed by regional governments represent 94% of the infrastructure in the health sector, the former purchasing medical devices through importing companies and the latter, including the Peruvian state and its institutions, with a public bidding process. They are all important partners for Swiss exporters.

Logistics and distribution: In Peru, in order to transport, deliver and ensure the quality and integrity of medical devices, establishments engaged in the manufacture, import, distribution, storage and dispensing of such products must comply with basic sanitary conditions, and also with the DIGEMID sectorial regulations, which are set out in the Manual of Good Distribution and Transport Practices. This manual establishes the minimum mandatory standards for the distribution and transport of pharmaceutical products and medical devices nationwide.

Case Studies: Testimonials from important firms -Roche, PANADEx- and medical groups -Association of Private Clinics of Peru, Health Association- illustrate key points of the report. Some issues and regulatory requirements are highlighted. The adoption of international standards and differences between the private and public sectors are also addressed. Opportunities are identified with health insurance programs which may represent the most promising market for exporting companies.

Conclusion: The report clearly shows that except for hearing aids and orthopedics, the Swiss presence on the Peruvian market is very small. Several Swiss products have nevertheless displayed a strong growth over the past years in some product categories while in other areas they are not represented. This points to significant business opportunities in a rapidly growing market. Bureaucratic and regulatory challenges, purchasing procedures by major users and access to public hospitals and clinics may be best addressed with a strong local representation.

3. MARKET OVERVIEW

Medical technology in Switzerland is highly competitive, due to its clusters of firms, scientific research and innovation. Peru has only a small number of manufacturers specialized in products with little added value. Most of the medical devices are therefore imported. In 2019, Switzerland had the largest market share in hearing aids and throat (26%) and orthopedics (19%). Its share was very low for ophthalmology (2%), surgical instruments (1.7%), disinfectants (1.3%), in-vitro-diagnostics (1.1%) and radiology imaging (0.9%).

What is Medtech?

The World Health Organization (WHO) defines Medtech as “the application of organized knowledge and skills in the form of medicines, medical devices, vaccines, procedures and systems developed to solve a health problem and improve quality of life¹”.

For Medtech Europe, this sector encompasses “products, services or solutions used to save and improve people's lives²”. Unlike the WHO, Medtech Europe does not include pharmaceuticals in its definition and focuses on: prevention (supporting in disease prevention, injury or other conditions); diagnosis (in-vitro diagnostics test results, which help to identify a specific condition, its development and subsequent treatment selection); monitoring (supporting patients in checking the status of a disease or chronic condition); treatment (helping patients overcome injuries and diseases or treating chronic illnesses) and, care (across the whole care pathway, accelerating recovery and keeping people healthy)³.

Statista⁴ includes in the Medtech industry most of all, medical devices which simplify the prevention, diagnosis and treatment of diseases and illnesses⁵. Likewise, it also does not include pharmaceuticals.

How important is Medtech?

Statista estimates medical technology revenues in 2019 close to US\$457.4 billion, to grow at 5 percent in 2022 and to reach US\$594.5 billion by 2024. The industry is dynamic with substantial investments on R&D (2017: US\$28.6 billion) and is led presently by the United States and Western Europe. However, according to industry trends, Asia and first of all China, are about to play a more prominent role in the years to come.

¹ Available on line: www.who.int/health-topics/medical-devices#tab=tab_1 (Accessed on 12/10/21)

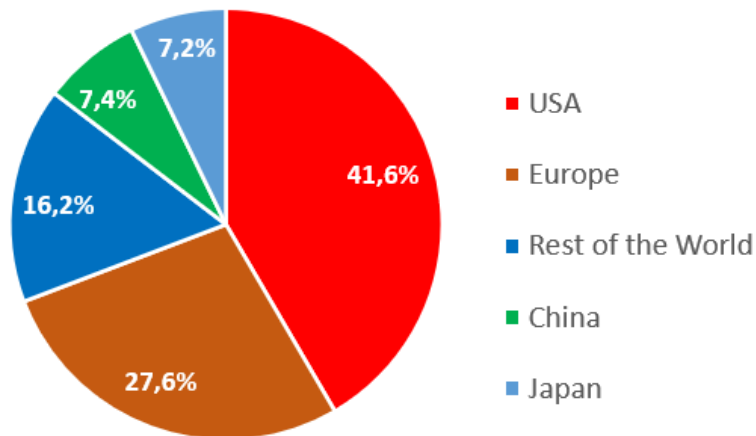
² Available on line: www.medtecheurope.org/about-the-industry/what-is-medical-technology/ (Accessed on 12/10/21)

³ Available on line: www.medtecheurope.org/about-the-industry/what-is-medical-technology/ (Accessed on 12/10/21)

⁴ Statista is a German online portal offering statistics from institute data, market and opinion research as well as data from the economic sector.

⁵ Available on line: www.statista.com/topics/1702/medical-technology-industry/ (Accessed on 12/10/21)

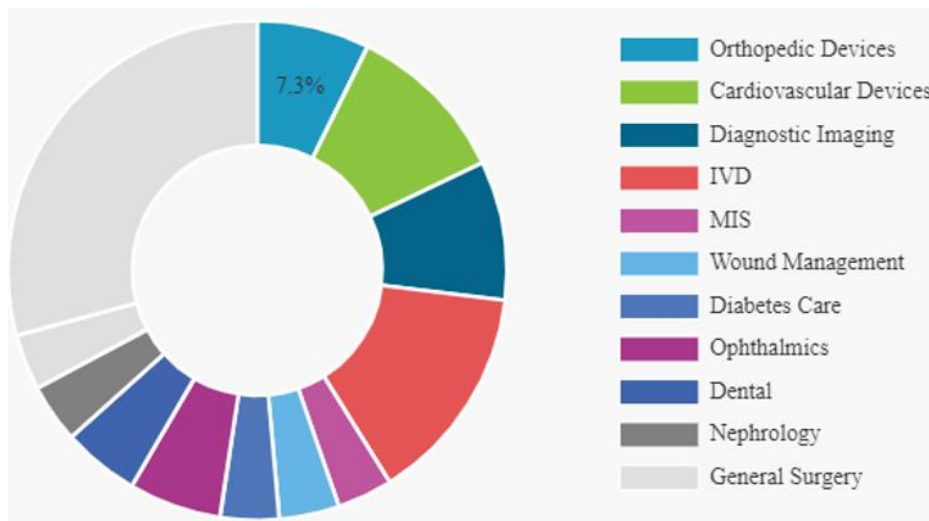
Figure 1. World medical devices market by region, 2020



Source: Medtech Europe
 Elaboration: Swiss Chamber of Commerce in Peru (CCSP)

Figure 1 shows the distribution of the manufacturers' income regarding medical devices in 2020. The United States represents 41.6% of the global sales, followed by Europe (27.6%), China (7.4%), Japan (7.2%) and the rest of the world (16.2%).

Figure 2. Medical devices market share by field, 2020

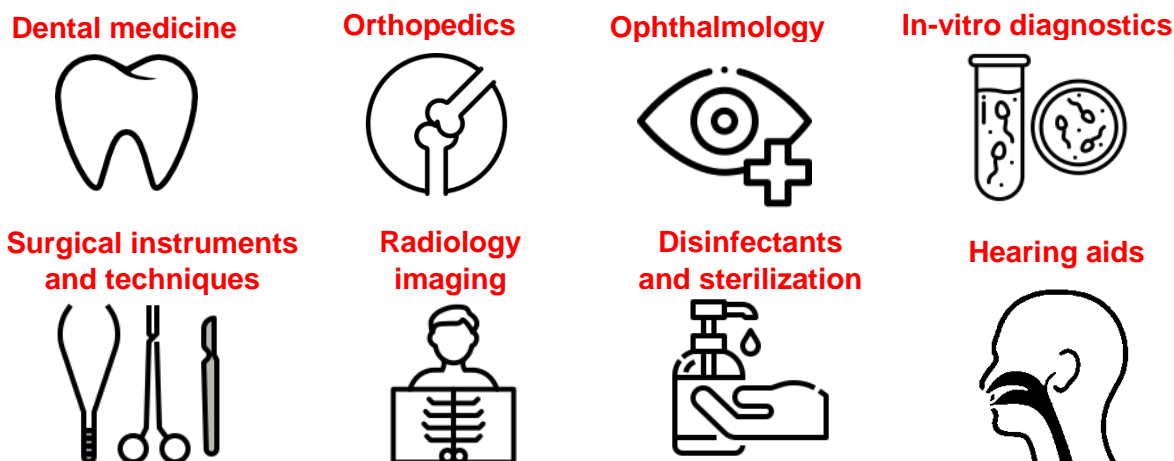


Source: Fortune Business Insight, Market Research Report, September 2021
 Note: MIS means minimal invasive surgery
 Available on line: [Medical Devices Market Size, Share, Trends | Analysis, 2028 \(fortunebusinessinsights.com\)](https://fortunebusinessinsights.com)

Figure 2 is particularly interesting as it showcases the relative importance of the various medical devices' categories.

Except for general surgery, which encompasses a large number of devices, in-vitro diagnostics has the biggest market share followed by cardiovascular devices, diagnostic imaging and orthopedic devices. Ophthalmic and dental medicine are also well positioned. The Swiss industry is active in all these fields and prone to benefit from a growing world market.

For this study, the following eight areas have been chosen because they account for most Swiss exports to the world and to Latin America.



3.1. Swiss Medtech exports to Peru

Swiss exports of Medtech products to Peru increased from SFR 12.05 million in 2017 to SFR 13.2 million in 2019. They decreased to SFR 9.11 million in 2020 due to the Covid crisis.

They were larger than SFR 1 million for orthopedics (SFR 3.8 million), surgical instruments and techniques (SFR 3.7 million), dental medicine (SFR 1.6 million) and ophthalmology (SFR 1.1 million).

In other product categories, Swiss exports remained very small. As an effect of the Covid crisis, they increased very significantly in 2020 for disinfectants and sterilization from SFR 0.2 million to SFR 0.9 million.

Between 2017 and 2019, Swiss Medtech exports to Peru increased (9.5%) more than Swiss Medtech exports to the world (6.2%), although from a small basis. Overall, the Peruvian market is gaining relevance for Swiss Medtech exports.

Swiss Medtech exports to Peru are further analyzed by category under 3.2.3.

3.2. Peru

Peru has only a very small industry producing medical devices. With a population of 33.5 million people⁶, the country imports practically all the products of the Medtech sector, which makes it an attractive market.



3.2.1. Peruvian health and insurance system

Peru's governments have repeatedly expressed that health is of vital importance. Several institutions manage the health sector's funds and their respective insurances, making it a very bureaucratic system. Several hospitals are under construction in the interior of the country; they will need Medtech devices before starting operations. The Peruvian health system consists of:

⁶ Available on line: [Peru Population 2021 \(Demographics, Maps, Graphs\) \(worldpopulationreview.com\)](https://www.worldpopulationreview.com/countries/peru-population-2021/) (Accessed on 17/01/22)

The Ministry of Health (MINSA), as the governing body, designates the directors of the administration of the regional governments as well as of the hospitals in the localities. It operates via the National Superintendence of Health – SUSALUD.

SUSALUD - National Superintendence of Health- belongs to the Ministry of Health. Its mission is to protect the health rights of all Peruvians by supervising that access to services is granted with quality, timeliness, availability and access regarding the Health or Insurance Institutions⁷. This entity is in charge of authorizations, audits, control and supervision of the good performance of health institutions (IPRESS and IAFAS).

- **IPRESS - Institutions Providing Health Services:** health facilities and medical support services, whether public, private or mixed, that provide health care in prevention, promotion, diagnosis, treatment and/or rehabilitation, as well as complementary or auxiliary services to medical care⁸.
- **IAFA - Health Insurance Funds Administration Institution:** in charge of collecting and managing funds for the insurance of health benefits and risk coverage of the insured⁹. Among them are the following:
 - **SIS - Integral Health Insurance**¹⁰ - Health Insurance Fund Management Institution whose purpose is to protect the health of Peruvians who do not have health insurance. It prioritizes vulnerable populations living in poverty and extreme poverty. The SIS has a subsidized and semi-contributory insurance. It covers medicines, procedures, surgeries, supplies and transfers according to the type of SIS of the user. It also has insurance for entrepreneurs, micro-enterprises and independent workers¹¹.
 - **ESSALUD - Peruvian Social Health Insurance**¹² - in charge of administering insurance funds for people who are formally employed. It has coverage for hazardous work and indemnity for accidents resulting in death. It also provides prevention, promotion, recovery, and rehabilitation, economic and social benefits¹³.
 - **IAFAS-FOSMAR**¹⁴ - Health risk coverage service, insurance plans and respective benefits for Military, Cadets and Students.
 - **IAFAS-EP**¹⁵ - Peruvian Army Health Insurance Fund Administration Institution.
 - **IAFAS-FOSFAP**¹⁶ - Health Insurance Fund Administration Institution of the Peruvian Air Force.
 - **SALUDPOL**¹⁷ - Health Insurance Fund of the Peruvian National Police.
 - **EPS - Health Provider Companies**¹⁸ - public or private companies other than ESSALUD that provide coverage in addition to ESSALUD's PEAS (Essential

⁷ Available on line: www.gob.pe/institucion/minsa/noticias/14866-conoce-mas-sobre-susalud-y-como-protege-los-derechos-en-salud-de-los-peruanos (Accessed on 02/11/21)

⁸ Available on line: www.gob.pe/institucion/minsa/noticias/14866-conoce-mas-sobre-susalud-y-como-protege-los-derechos-en-salud-de-los-peruanos

⁹ Available on line: www.gob.pe/institucion/minsa/noticias/14866-conoce-mas-sobre-susalud-y-como-protege-los-derechos-en-salud-de-los-peruanos

¹⁰ Available on line: www.gob.pe/4289-seguro-integral-de-salud-que-hacemos (Accessed on 02/11/21)

¹¹ Available on line: www.gob.pe/281-seguros-de-salud-del-peru (Accessed on 10/11/21)

¹² Available on line: <http://portal.essalud.gob.pe/> (Accessed on 02/11/21)

¹³ Available on line: www.gob.pe/281-seguros-de-salud-del-peru (Accessed on 10/11/21)

¹⁴ Available on line: <https://iafasfosmar.pe/> (Accessed on 02/11/21)

¹⁵ Available on line: <https://iafasep.gob.pe/> (Accessed on 02/11/21)

¹⁶ Available on line: <https://iafasfap.gob.pe/> (Accessed on 02/11/21)

¹⁷ Available on line: www.gob.pe/4505-fondo-de-aseguramiento-en-salud-de-la-policia-nacional-del-peru-que-hacemos (Accessed on 02/11/21)

¹⁸ Available on line: www.gob.pe/281-seguros-de-salud-del-peru (Accessed on 02/11/21)

Health Insurance Plan) coverage. Employers can contract an EPS to provide additional coverage to the PEAS for their employees.

- **Prepagas - Prepaid Health Services Provider Entity**¹⁹ - Insurance belonging to a clinic that operates in an integrated manner as a business unit complementary to the rendering units.
- **Autoseguro**²⁰ - Health insurance of a professional group, a work group or an organized entity or society that is financed by the contribution of its members with the eventual participation of the employing entity, directly assuming the risk of health insurance.
- **Health Insurance Companies.**
- **AFOCAT - Association of Regional or Provincial Funds against Traffic Accidents**²¹ - it is an alternative to insurance companies in the issuance of the Compulsory Insurance against Traffic Accidents (SOAT) for public transport units. These are non-profit organizations composed of transport operators of a specific area (province or region) who contribute to a fund for covering expenses related to traffic accident of members.

Peru has a decentralized health care system with the Ministry of Health (MINSA) (60% of the population), EsSalud (30%), and, the Armed Forces (FFAA), the National Police (PNP) and the private sector for the remaining 10%. This system has weaknesses with numerous service and insurance providers, which are poorly coordinated with often overlapping functions. The geographic distribution of health facilities is uneven; Lima and coastal areas have the highest densities of health facilities, while the regions of Piura, Lambayeque and Loreto have the lowest ones²².

State health insurance allows to receive medical treatment in Public Health Care Institutions (IPRESS), depending on the type of regime in which the person is enrolled. The two most widely used are the Integral Health Insurance (SIS) and the Peruvian Social Health Insurance (EsSalud)²³.

“There is no difference between the various public health insurance schemes (SIS, IAFAS or the Armed Forces): they pay for all the needs of the patients. Private insurers act differently. They audit the treatment of the patient. For example, if one uses a medical device that is not included in the health coverage, they will not pay for it.”

*Lima Chamber of Commerce
Health Association*

Health Provider Companies (EPS) are public or private companies other than EsSalud that provide additional coverage to EsSalud's Essential Health Insurance Plan (PEAS). Employers can contract an EPS to provide additional coverage to the PEAS for their employees. There are four EPS companies in Peru: Rimac, Mapfre, Sanitas and Pacífico²⁴.

¹⁹ Available on line: <http://acp.org.pe/entrevistas/entidades-prestadoras-de-servicios-de-salud-prepagados/> (Accessed on 02/11/21)

²⁰ Available on line: <https://cdn.www.gob.pe/uploads/document/file/1420029/Resoluci%C3%B3n%20de%20Superintendencia%20N%C2%B0%20106-2020-SUSALUD-S-c%20%281%29.pdf.pdf> (Accessed on 02/11/21)

²¹ Available on line: www.apeseg.org.pe/2018/07/que-es-la-afocat/ (Accessed on 02/11/21)

²² Available on line: www.who.int/workforcealliance/countries/per/es/ (Accessed on 09/11/21)

²³ Available on line: www.gob.pe/281-seguros-de-salud-del-peru (Accessed on 10/11/21)

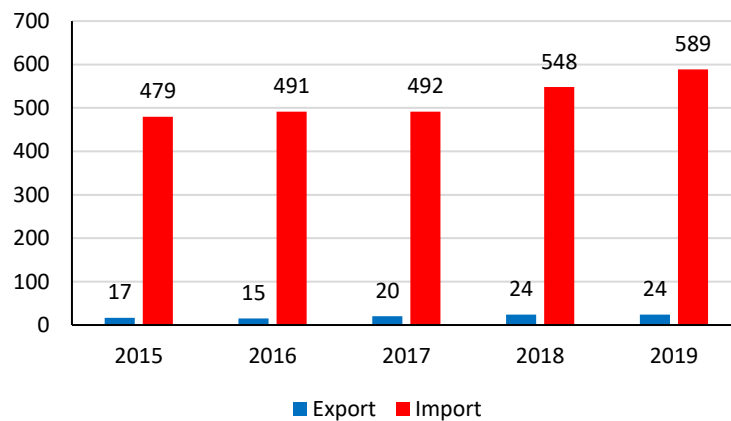
²⁴ Available on line: www.gob.pe/281-seguros-de-salud-del-peru (Accessed on 10/11/21)

3.2.2. Peru's market for Medtech products

As illustrated in Figure 3, Peru is a large market for Medtech products with US\$589 million imports in 2019. Domestic production is fairly small.

“Approximately 95% of medical devices are imported and 5% are manufactured domestically. Sutures, gauze, syringes, catheters, disinfectants, orthopedics (limb replacement) are produced in Peru. Technology is not sufficiently advanced in Peru for local production”
Lima Chamber of Commerce, Health Association

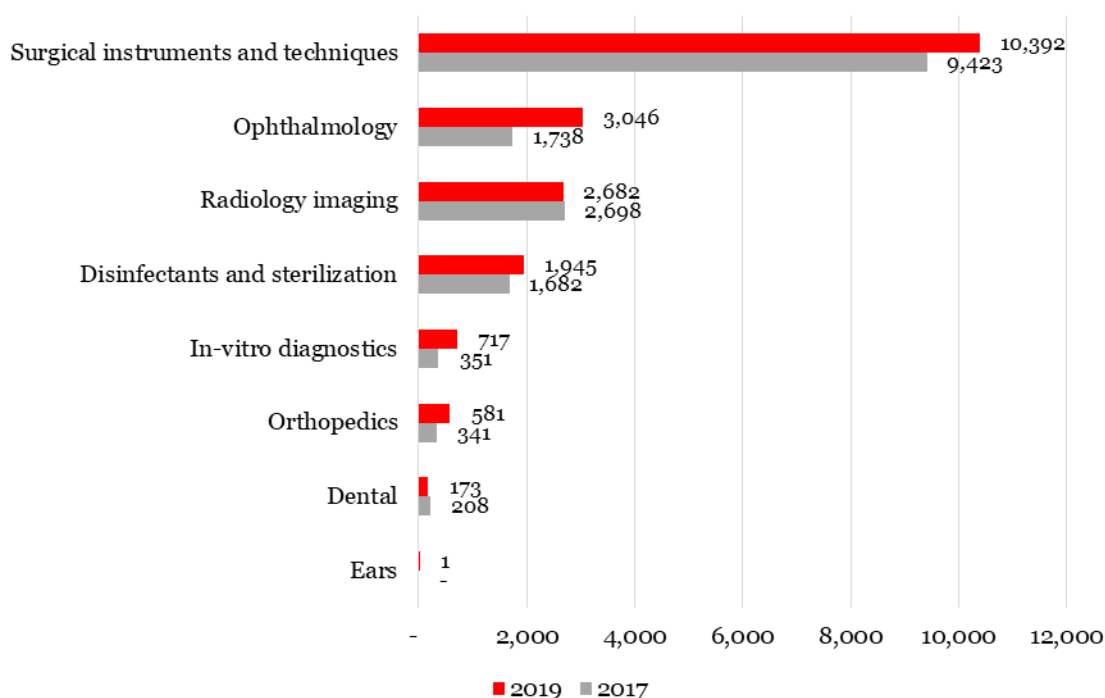
Figure 3. Peruvian medical devices exports and imports, 2015-2019
(US\$ millions)



Source: Comtrade. Elaboration: Swiss Chamber of Commerce in Peru (CCSP)

Peru's exports of Medtech products are small and do not exceed US\$3 million for the major categories except surgical instruments and techniques (US\$10.4 million). The larger exports by product category in 2017 and 2019 are presented in Figure 4.

Figure 4. Peruvian exports of Medtech products by category, 2017, 2019
(US\$ thousands)



Source: Comtrade.

Elaboration: Swiss Chamber of Commerce in Peru (CCSP)

At a product level (table 1), sterile materials lead by far Peru's Medtech exports followed by instruments, disinfectants, frames and mountings. Peru's position is smaller for magnetic resonance apparatus, in-vitro diagnostics, X-ray tubes and generators, and orthopedic appliances. Exports are very small for dental fittings and hearing aids.

Table 1. Largest Peruvian Medtech exports by product, 2019

Category	Product	2019 (US\$ thousands)
Surgical instruments and techniques	Sterile materials (HS 3006.10)	6,735
Surgical instruments and techniques	Medical, surgical or dental instruments and appliances (HS 9018.90)	1,234
Disinfectants and sterilization	Disinfectants and similar products (HS 3808.94)	1,777
Ophthalmology	Frames and mountings; for spectacles, goggles or the like, of plastics (HS 9003.11)	1,286
Radiology imaging	Magnetic resonance imaging apparatus (HS 9018.13)	739
Radiology imaging	X-ray tubes (HS 9022.30)	691
Radiology imaging	X-ray generators other than X-ray tubes, high tension generators, control panels and desks, screens, examination or treatment tables, chairs and the like (HS 9022.90)	549
In-vitro diagnostics	Diagnostic or laboratory reagents (HS 3822.00)	717
Orthopedics	Orthopedic or fracture appliances (HS 9021.10)	579
Dental medicine	Dental fittings (HS 9021.29)	115
Hearing aids	Hearing aids (HS 9021.40)	1

Source: Comtrade.

Elaboration: Swiss Chamber of Commerce in Peru (CCSP).

Peruvian exports and local production in the Medtech sector being small, imports represent almost the total market.

At the end of 2021, the budget for the Health sector was increased by 6% for 2022 and has among its priorities the financing of the prevention and care of the pandemic against COVID-19. This increase in the budget will allow financing prevention, control, surveillance and health response actions, as well as the purchase of vaccines²⁵.

Minister Cevallos (now ex-Minister) indicated that the acquisition of personal protective equipment, medicines, medical supplies, medical oxygen, among others, has been assured, ensuring the continuity of operations in care centers, temporary isolation and health facilities²⁶.

Among the main programmed objectives, supported by the Minister, are: to reduce by 10% the prevalence of anemia in children from 6 months to 3 years of age, to achieve complete vaccination of children under 14 months, to provide a greater and better service in the level of care for pregnant mothers and coverage of antiretroviral treatment for people infected with the human immunodeficiency virus (HIV). He also said that care for tuberculosis patients, women suffering from cervical cancer and for those over 5 years of age suffering from diabetes mellitus will be improved²⁷.

Regarding the hospitals to be delivered, Essalud has committed to deliver 10 high complexity hospitals (located in the departments of Puno, Cajamarca, Piura, Chimbote, Cerro de Pasco, La Libertad, Ica, and Lima (Angamos and Vitarte) as well as 15 fast-track hospitals (located in the departments of Cajamarca, Lima, Huanuco, Amazonas, San Martin and Loreto) by 2022. In this sense, the supply of medical equipment must be paramount to guarantee the start-up of each center²⁸.

3.2.3. Peruvian Medtech imports from the world and from Switzerland

Peruvian Medtech imports increased from US\$417.7 million in 2017 to US\$511 million in 2019. They were larger than US\$10 million for every category except for hearing aids (US\$3.4 million in 2019). In terms of growth rates Peruvian imports increased by 22.3% (2017-2019).

The following figures present Peru's imports in the eight categories selected for this report from the world and Swiss exports to Peru. The categories are presented by order of importance for Peru.

Peru's imports from Switzerland and Swiss exports to Peru were divided in large-size, medium-size and small-size imports corresponding to \$1million and more, \$0.1 to \$0.9 million and less than \$0.1 million respectively. Minor classification differences of products between the Swiss and the Peruvian customs authorities are noted.

²⁵ Available online: www.gob.pe/institucion/minsa/noticias/563378-presupuesto-del-sector-salud-permitira-financiar-lucha-contra-la-covid-19-anemia-cancer-y-otros-programas-de-salud-publica

²⁶ Available online: www.gob.pe/institucion/minsa/noticias/563378-presupuesto-del-sector-salud-permitira-financiar-lucha-contra-la-covid-19-anemia-cancer-y-otros-programas-de-salud-publica

²⁷ Available online: www.gob.pe/institucion/minsa/noticias/563378-presupuesto-del-sector-salud-permitira-financiar-lucha-contra-la-covid-19-anemia-cancer-y-otros-programas-de-salud-publica

²⁸ Available online: <https://elperuano.pe/noticia/135755-essalud-construira-10-hospitales-de-alta-complejidad-en-el-2022>

Figure 5. Peru's imports from the world of surgical instruments and techniques, 2017-2019 (US\$ millions)

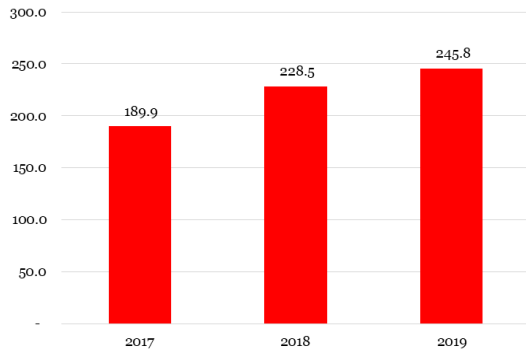
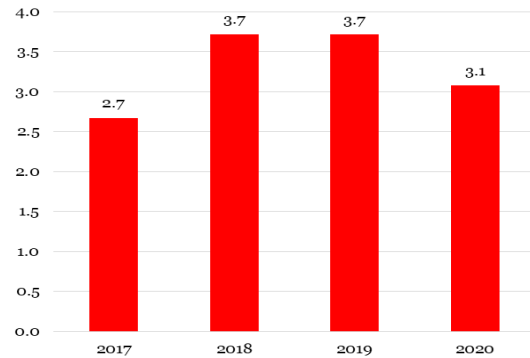


Figure 6. Switzerland exports to Peru of surgical instruments and techniques, 2017-2020 (US\$ millions)



Source: Comtrade and Swissimpex. The same source applies to figures 5-20
 Elaboration: Swiss Chamber of Commerce in Peru (CCSP) for figures 5-20.



Peru's imports of surgical instruments and techniques registered a strong growth rate (29.4%) between 2017 and 2019 reaching US\$245.8 million. With \$3.7 million, Switzerland had a very small share of the market (1.7% of imports)²⁹.

Large-size imports from Switzerland include medical, surgical or dental instruments (HS 9018.90) and ozone, oxygen or aerosol therapy (HS 9019.2). Catheters, cannulae and the like (HS 9018.39) belongs also to that category, but only in Peru's statistics. Peru's medium-size imports from Switzerland match Switzerland only for syringes (HS 9018.31) and tubular metal needles (HS 9018.32), all the remaining products (adhesive dressings (HS 3005.10), wadding, gauze, bandages (HS 3005.90) being in the small-size category in Swiss data.

It is also useful to point to the products not imported from Switzerland: rubber, surgical gloves (HS 4015.11), ultrasonic scanning apparatus (HS 9018.12) and, pacemakers for stimulating heart muscles (HS 9021.50).

Figure 7. Peru's imports from the world of radiology imaging products, 2017-2019 (US\$ millions)

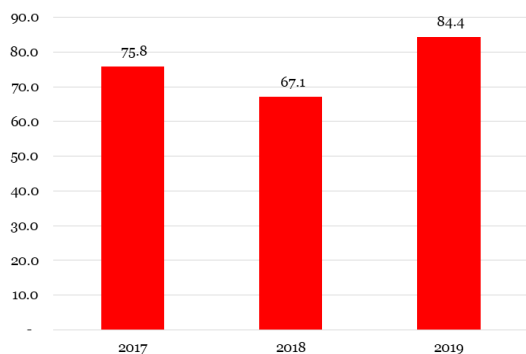
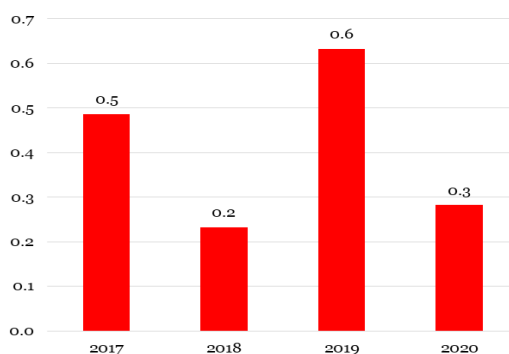


Figure 8. Switzerland's exports to Peru of radiology imaging products, 2017-2020 (US\$ millions)



²⁹ Exchange rate of 1 US\$ = 0.9159 SFR as of October 31, 2021. Available on line: www.xe.com/es (Accessed on 31/10/21). The same exchange rate applies for figures 13, 15, 17, 19, 21, 23 and 25.



Imports of radiology imaging products grew by 11.3% between 2017 and 2019 for total imports of US\$84.4 million. With US\$0.6 million, Switzerland had a very small share of the market (0.8% of imports).

No trade takes place in the large-size category. In the medium-size category, in addition to X ray generators (HS 9018.19) and apparatus (9022.19), Swiss data registers also exports of X-ray generators (HS 9022.90). Small imports include X-ray tubes (HS 9022.30) and electro-cardiographs (HS 9018.11). Ultraviolet or infra-red ray apparatus used in medical sciences (HS 9018.20) has only been registered as a Swiss export to Peru.

It is also useful to point that a fairly large range of products purchased by Peru in this category were not exported by Switzerland: opacifying preparations for x-ray examinations (HS 3006.30), magnetic resonance imaging apparatus (HS 9018.13), scintigraphic apparatus (HS 9018.14), apparatus based on the use of x-rays, (HS 9022.12), apparatus based on the use of x-rays, for dental uses (HS 9022.13) and for medical, not dental uses (HS 9022.14), apparatus based on the use of alpha, beta or gamma radiations (HS 9022.21) and for other than medical, surgical, dental or veterinary uses (HS 9022.29).

Figure 9. Peru's imports from the world of ophthalmology products, 2017-2019
(US\$ millions)

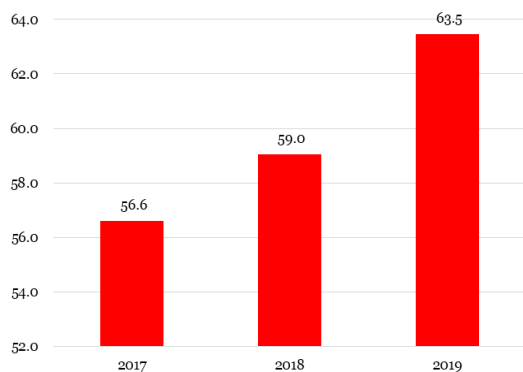
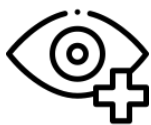
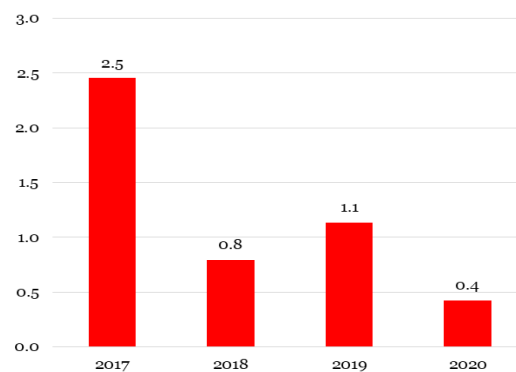


Figure 10. Switzerland's exports to Peru of ophthalmology products, 2017-2020
(US\$ millions)



Peru's imports of ophthalmology products increased by 12% between 2017 and 2019 reaching US\$63.5 million. With US\$1.1 million, Switzerland had a very small share of the market representing 2% of imports.

Large imports from Switzerland include ophthalmic instruments and appliances (HS 9018.50) and small ones, spectacles, goggles and the like, corrective, protective or other (HS 9004.90); glasses for corrective spectacles (HS 7015.10) and spectacle lenses of glass optically worked (HS 9001.40) are only registered in the Swiss data as small-size exports to Peru.

It may be noted that Peru did not import several products from Switzerland: contact lenses (HS 9001.30), lenses, spectacle; unmounted, of materials other than glass (HS 9001.50), frames and mountings; for spectacles, goggles or the like, of plastics (HS 9003.11) and of materials other than plastics (HS 9003.19) and parts or the like (HS 9003.90).

Figure 11. Peru's imports from the world of in-vitro diagnostics products, 2017-2019
(US\$ millions)

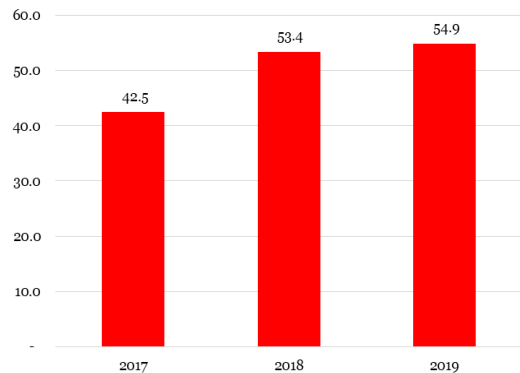
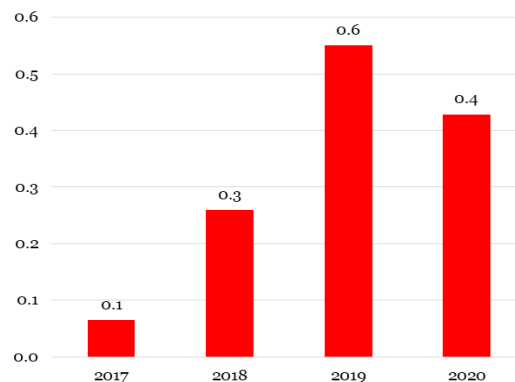


Figure 12. Switzerland's exports to Peru of in-vitro diagnostics products, 2017-2020
(US\$ millions)



Imports of in-vitro diagnostics products grew by 29.4% between 2017 and 2019 for total imports of US\$54.9 million. With US\$0.6 million, Switzerland had a very small share of the market representing 1.1% of imports. Swiss exports of reagents for determining blood groups or blood factors (HS 3006.20) grew very significantly (2017-19: +755%). Swiss firms such as Roche, Pentapharm and Spericalplate 5D are world leaders in various types of diagnostics.

Swiss and Peruvian data converge with only reagents (HS 3006.20) in the medium-size category. It is also useful to point that, according to Peru's trade statistics, Peru did not import any diagnostic or laboratory reagents (HS 3822.00) from Switzerland, while Swiss data ranged in the small-size category.

Figure 13. Peru's imports from the world of orthopedic products, 2017-2019
(US\$ millions)

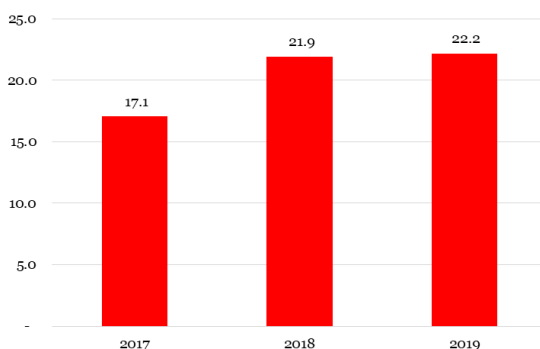
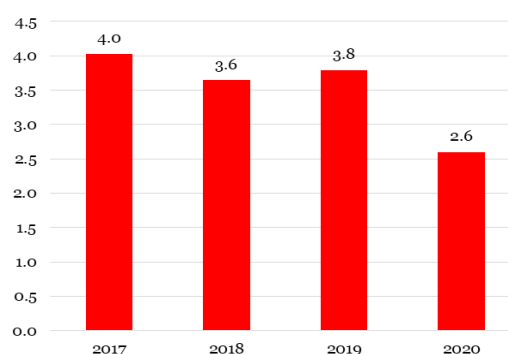


Figure 14. Switzerland's exports to Peru of orthopedic products, 2017-2020
(US\$ millions)



Peru's imports of orthopedic products grew by 30.1% between 2017 and 2019 for total imports of US\$22.2 million in that year. With US\$3.8 million, Switzerland had a fairly substantial share of the market (18.7% of imports). Switzerland has a strong position in the world for orthopedics with firms such as Zimmer Biomet, Medacta, Medartis and Geistlich.

For large-size imports Peru's data matches Switzerland with orthopedic or fracture appliances (HS 9021.10). Artificial parts of the body (HS 9021.31) fall under medium-size for Peru and small size for Switzerland.

Figure 15. Peru's imports from the world of dental products, 2017-2019
(US\$ millions)

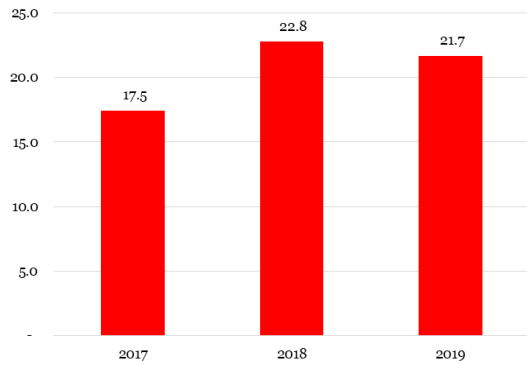
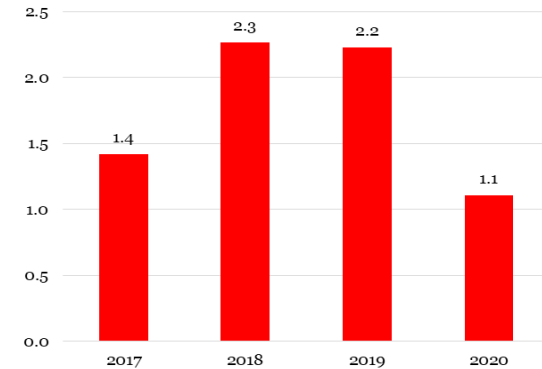


Figure 16. Switzerland's exports to Peru of dental products, 2017-2020
(US\$ millions)



Imports of dental products registered a growth rate of 24.10% between 2017 and 2019 for total imports of US\$21.7 million in that year. With US\$2.2 million and 12.2% of imports, Switzerland was well positioned in the market.

Peru and Swiss data converge in the large size category for instruments and appliances used in dental sciences (HS 9018.49) to which Switzerland adds dental cements, fillings and bone reconstruction cements (HS 3006.40). Medium-size imports include dental fittings (HS 9021.29). It is useful to note that dental floss (HS 3306.20), dental drill engines (HS 9018.41) and artificial teeth (HS 9021.21) are only registered in the Swiss data under exports to Peru.

Figure 17. Peru's imports from the world of disinfectants and sterilization products, 2017-2019
(US\$ millions)

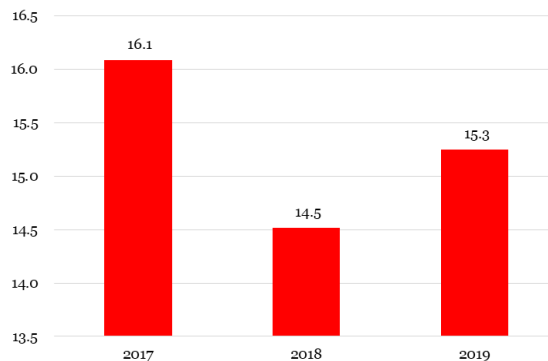
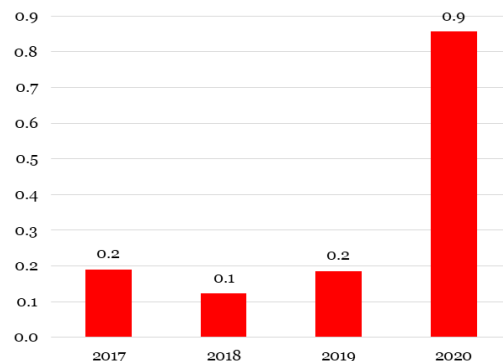


Figure 18. Switzerland's exports to Peru of disinfectants and sterilization products, 2017-2020
(US\$ millions)



Peru's imports of disinfectants and sterilization products declined by 5.20% between 2017 and 2019 for total imports of US\$15.3 million in that year. With US\$0.2 million, Switzerland had a very small share of the market representing 1.3% of imports.

Disinfectants and similar products (HS 3808.94) are in the small- (Peru) and medium-size (Switzerland) categories respectively. It is useful to note that medical, surgical and laboratory sterilizers (HS 8419.20) is only showcased as small-size in Swiss data.

Figure 19. Peru's imports from the world of hearing aids, 2017-2019
(US\$ millions)

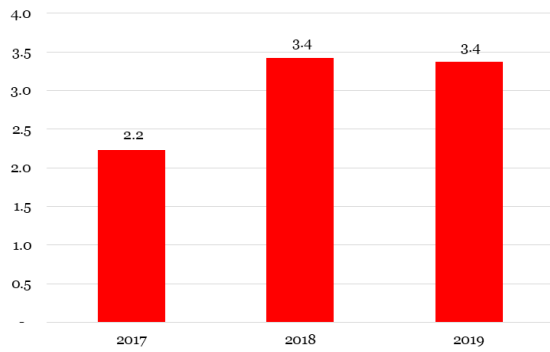
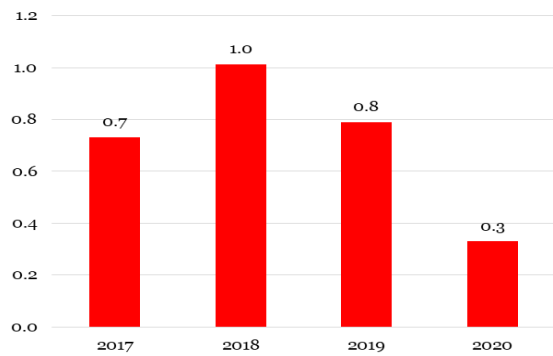


Figure 20. Switzerland's exports to Peru of hearing aids, 2017-2020
(US\$ millions)



Imports of hearing aids grew by 51.1% between 2017 and 2019 for total imports of US\$3.4 million in that year. With US\$0.8 million, Switzerland had a large share of the market representing 25.6% of imports. With the firm Sonova, Switzerland is a world leader in hearing aids.

While Switzerland classifies hearing aids (HS 9021.40) in the large-size category, Peru does so in the medium-size.

4. REGULATORY OVERVIEW

Regulatory requirements referring to registration, market authorization and supervision of medical devices are one of the most difficult aspects to manage. To seek a sanitary registration with the General Directorate of Medicines, Inputs and Drugs, a Swiss firm can either set up in Peru a company called "Droguería" or request the services of a local company. A technical dossier must be prepared for each type of medical device. The whole process takes place virtually through the Foreign Trade Single Window.

The legal framework that promotes and facilitates business between Peru and Switzerland is based on:

- The Agreement between the Republic of Peru and the Swiss Confederation on the Promotion and Reciprocal Protection of Investments (1991).
Available on line: <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/2163/download> (English)
- The Free Trade Agreement between the Republic of Peru and the European Free Trade Association (EFTA) States.
Available on line: www.acuerdoscomerciales.gob.pe/En_Vigencia/EFTA/Documentos/ingles/Acuerdo_Principal.pdf (English)
- The Convention between the Republic of Peru and the Swiss Confederation for the avoidance of double taxation with respect to taxes on income and wealth and its protocol (2012).
Available on line: www.mef.gob.pe/contenidos/tributos/cv_dbl_imp/Convenio_Peru_Suiza_DT.pdf (Spanish)

4.1. Custom tariffs

Peru currently applies the following tariffs upon imports: (a) ad valorem tariffs of 0%, 6% and 11%, and (b) specific tariffs. There is a 0% tariff on 69.9% of tariff lines, which in 2018 accounted for 74% of imports in terms of value (WTO, 2020)³⁰.



The Free Trade Agreement between Peru and the States of the European Free Trade Association (EFTA), of which Switzerland, Liechtenstein, Norway and Iceland are members, was signed in Reykjavik on June 24, 2010 and in Lima on July 14, 2010. According to this agreement, all those products that present a certificate of origin³¹ will benefit from 100% liberalization of the Ad Valorem tariff. If they do not have this certificate, the customs duties upon imports into Peru are, for a total of 59 Medtech products, the following: 76% of the products are not subject to any tariff and 24% have a tariff of 6%.

4.2. Trade remedies

Trade remedies include anti-dumping duties, countervailing measures or safeguards measures. Trade remedies are trade policy tools that allow governments to take remedial action against imports. Peru does not apply any trade remedy on Medtech products.

³⁰ World Trade Organization (5 February 2020) Trade Policy Review Body - Trade Policy Review - Report by Peru - Revision. Available on line:

<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/TPR/G393R1.pdf&Open=True>

³¹ The document that certifies compliance with the origin requirements, in accordance with the provisions of the corresponding trade agreement or preferential regime.

4.3. Regulatory requirements

Medtech products are subject to different national standards. Law No. 29459 on Pharmaceuticals, Medical Devices and Sanitary Products³² establishes the general regulatory framework to define the principles, standards, criteria and basic requirements for pharmaceuticals, medical devices and sanitary products. According to this law, medical devices are defined as any instrument, apparatus, implement, machine, reagent or in-vitro calibrator, computer application, material or other similar article, intended by the manufacturer to be used in human beings, alone or in combination, for one or more of the following specific purposes:



- a) Diagnosis, prevention, monitoring, treatment or alleviation of a disease.
- b) Diagnosis, monitoring, treatment, alleviation or compensation of an injury.
- c) Investigation, replacement, modification or support of anatomy or physiological process.
- d) Support or maintenance of life.
- e) Control of conception.
- f) Disinfection of medical devices.

In order to introduce a Medtech product on the Peruvian market, it is necessary to establish or to work with a drugstore to register the product.

4.3.1. Establishment of a drugstore

The sanitary registrations for Medtech products can only be carried out by a company incorporated in Peru. Such a company is called a "Droguería". It is a constituted company with its Single Taxpayer Registry (RUC), a fiscal domicile (administrative office), a specialized staff (pharmaceutical chemist) and a warehouse (own or outsourced warehouse).

Swiss companies can choose between establishing their own company in Peru or requesting the services of an existing "Droguería". The second option is mostly used since much time can be saved.

4.3.2. Registrations and certifications

"Droguerías" can submit documents for product registrations. Each product has a technical dossier containing the manufacturer's or supplier's information. To prepare the technical file for applications for medical device health registrations, the requirements established in DS 016-2011/SA³³ and its amendments must be taken into account. Applications are submitted virtually through the Single Window for Foreign Trade



– VUCE. It should be noted that the time to obtain the registrations depends on the type of medical device. For imported medical devices, the documents must be submitted in the original language with a translation into Spanish.

³² Available on line: www.digemid.minsa.gob.pe/normas-legales/2009/11/ID=3640/ley-n-29459

³³ Available on line: https://cdn.www.gob.pe/uploads/document/file/272181/243290_16_-_DS_N_C2_B0_016-2011-SA.pdf20190110-18386-a4eggt.pdf

The requirements vary according to the type of product. Thus, medical devices are classified according to the general system of the General Directorate of Medicines, Inputs and Drugs (DIGEMID) as follows³⁴:

- **Class I (Low Risk):** medical devices subject to general controls, not intended to protect or maintain life or for a use of special importance in the prevention of deterioration of human health and if not used there is not a reasonable potential risk of disease or injury.
- **Class II (Moderate risk):** medical devices subject to special controls in the manufacturing phase to demonstrate their safety.
- **Class III (High risk):** medical devices subject to special design and manufacturing controls to demonstrate their safety and efficacy.
- **Class IV (Risk Critical):** medical devices subject to special controls, intended to protect or sustain life or to prevent deterioration of human health; if not used, there is a potential risk of illness or injury.

“Not all products fit in DIGEMID classification, there is a legal void. Problems generally occur in devices because sometimes they do not fit within the standards applied to all medical products (pharma, devices, natural products, equipment). The standards were made with a "pharma" criterion and were modified little by little. This is one of the reasons why there are very few manufacturing companies in the country”
Lima Chamber of Commerce Health Association

Table 2: Summary of Requirements for Medical Devices in Peru

Requirement	Class I	Class II	Class III	Class IV
Affidavit Request	✓	✓	✓	✓
Certificate of Free Commercialization	✓	✓	✓	✓
Certificate of Good Manufacturing Practices	✓	✓	✓	✓
Technical report of the medical device	✓	✓	✓	✓
Technical studies and analytical checks	✓	✓	✓	✓
Sterilization or calibration process validation report (if applicable)	✓	✓	✓	✓
Waste method (if applicable)	✓	✓	✓	✓
Immediate and mediate labeling project (as applicable)	✓	✓	✓	✓
Instructions for use manual content (if applicable)	✓	✓	✓	✓
Risk analysis report (according to ISO standard)	X	✓	✓	✓
Technical information on safety and efficacy of the medical device. Quality Parameters (according to ISO, FDA or CE standard or other internationally recognized document)	X	✓	✓	✓
Clinical trials on safety and efficacy of the medical device	X	X	✓	✓
List of countries where the device is marketed	X	X	✓	✓
Post-marketing surveillance program	X	X	✓	✓

Source: DS 016-2011/SA
 Available on line: https://cdn.www.gob.pe/uploads/document/file/272181/243290_16_-_DS_N_C2_B0_016-2011-SA.pdf20190110-18386-a4eggt.pdf

³⁴ Available on line: www.digemid.minsa.gob.pe/UpLoad/UpLoaded/PDF/Publicaciones/DocumentosVarios/P32_2012-12-21_Directiva_Peru.pdf

Additional considerations

If the product is imported, it is necessary to present the Certificate of Free Commercialization and the Certificate of Use. According to Directorial Resolution³⁵ No. 169-2014-DIGEMID-DG-MINSA, the competent foreign authority must issue certificates of free marketing for medical devices as follows for Switzerland:

SERVICE OF MEDICAL DEVICES SWISS FEDERAL OFFICE OF PUBLIC HEALTH
Postal Address: CH-3003 BERNE
Switzerland
Issued: Certificate of Free Marketing will include the phrase "Is used".
SWISS AGENCY FOR THERAPEUTIC PRODUCTS SWISSMEDIC
Hallestrasse 7.Postfach.Ch-3000 Bern9
www.swissmedic.ch/md.asp

The labelling of the packages or the information accompanying the product must include the following information:

- a) Product name.
- b) Indications, instructions and precautions for use.
- c) Net content for supplies and instruments.
- d) Name of the country and laboratory or manufacturing company.
- e) Sanitary registration number.
- f) Batch or serial number, as applicable.
- g) Unified registration number.
- h) Name or company name and address of importer.
- i) Expiration date for sterile or perishable products.
- j) Storage conditions for supplies and instruments that require it.
- k) Date of manufacture; model and code; and pre-installation conditions for equipment.

4.3.3. Special authorizations

In addition to customs documentation, some products called "Restricted Goods" require upon import permits and authorizations issued by State entities in charge of controlling and supervising them. To determine if a product is a "restricted good" it is necessary to consult National Superintendence of Customs and Tax Administration - SUNAT's virtual platform: www.aduanet.gob.pe/itarancel/arancelS01Alias

There is a large variety of restricted products. Table 5 provides a few examples for each of the eight categories of Medtech products analysed in this report. It shows that most products are reviewed by DIGEMID, with the exception of X-ray tubes, which are under the Peruvian Institute of Nuclear Energy (IPEN).

³⁵ Available on line:

www.digemid.minsa.gob.pe/UpLoad/UpLoaded/PDF/DAS/Listado_autoridades_competentes.pdf

Table 3. Restricted products requiring authorization

Category	Product with HS tariff number	Products (Peruvian classification)	Control Agency
Surgical instruments and techniques	Instruments and appliances used in medical or surgical sciences (HS 9018.90)	Audiometers, cardio defibrillator, electrosurgical scalpel, cardiovascular laser surgery equipment, Holter system, lithotripsy system, etc.	DIGEMID
Disinfectants and sterilization	Disinfectants and similar products (HS 3808.94)	Antimicrobial detergent for medical surgical or dental instruments, cold sterilizers, etc.	DIGEMID
Ophthalmology	Contact lenses (HS 9001.30)	Contact lenses.	DIGEMID
Radiology imaging	X-ray tubes (HS 9022.30)	X-ray tubes.	IPEN ³⁶
In-vitro diagnostics	Diagnostic or laboratory reagents (HS 3822.00)	Reagents for molecular typing, anticoagulant reagents, reagents for lymphocyte counting, etc.	DIGEMID
Orthopedic	Orthopedic or fracture appliances (HS 9021.10)	Collars, prostheses and implants for internal use.	DIGEMID
Dental medicine	Dental fittings (HS 9021.29)	Brushes for polishing, instruments for endodontic, instruments for dental surgery, instruments for orthodontics, scissors for maxillofacial surgery, etc.	DIGEMID
Hearing aids	Hearing aids (HS 9021.40)	Hearing aids.	DIGEMID

Source: Superintendencia Nacional de Aduanas y de Administración Tributaria - SUNAT.
Available on line: www.aduanet.gob.pe/itarancel/arancelS01Alias

“It is important to select well the product to be introduced in Peru, to be able to register it according to Peru’s legal conditions, to have a strategic commercial partner to present the properties and advantages of the product to the clinics and hospitals, and who knows the different procedures of each institution.”

*Lima Chamber of Commerce
Health Association*

³⁶ Institute of Nuclear Energy

5. OPPORTUNITIES AND CHALLENGES

Swiss products are well represented in the high growth categories, although at modest levels. There is significant potential, equally in some other categories based on Swiss technology. Important hurdles are related to lack of flexibility in procedures and absence of agreements with agencies of the United States and the European Union. The business climate is also strongly affected by the country's unstable political climate, lack of legal security, weak protection of intellectual property, informality and corruption.



This chapter seeks to identify opportunities and challenges for Swiss exports of Medtech products to Peru. The analysis is based on a comparison of Peru's imports from Switzerland over a 10-year period at a 6-digit level with Peru's import from the world. The results allow to identify Swiss products that are taking advantage of the opportunities of the Peruvian market, Swiss products that could benefit more from Peru's market potential, and Swiss products facing a declining demand in Peru.

"A product, just by the fact that it is from Switzerland, is already an endorsement. Everyone thinks that Swiss products are more accurate and precise."

*Lima Chamber of Commerce
Health Association*

5.1. Medtech opportunities

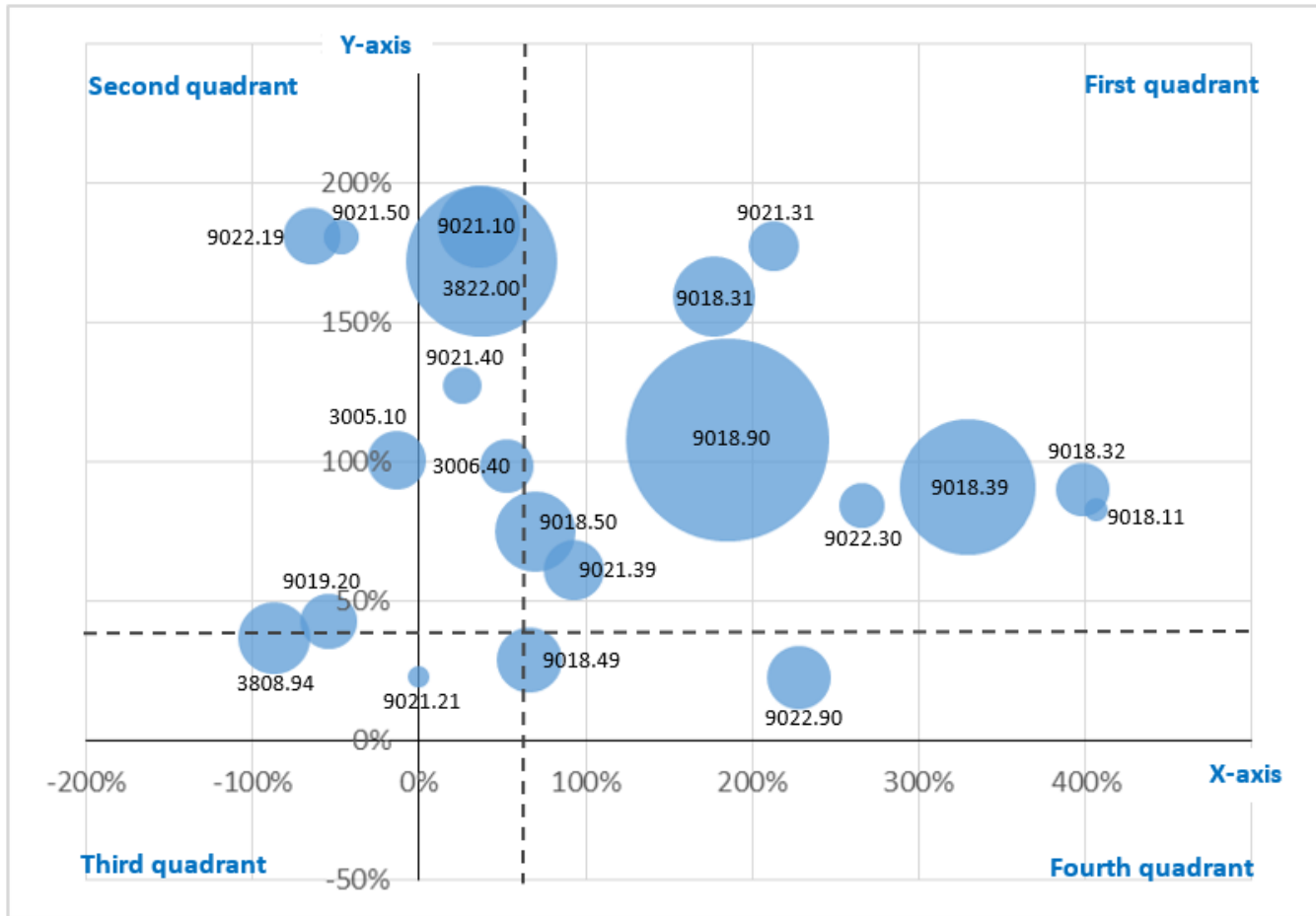
Figure 26 presents a four-quadrant graph with Peru's key Medtech imports from Switzerland at 6-digit level. The horizontal axis (X-axis) features the growth rates of Peru's imports from Switzerland and the vertical axis (Y-axis) features Peru's imports from the world. The size of Peru's import market is showcased with bubbles representing Peru's total imports from the world in 2019. The four quadrants are within dotted lines. The vertical dotted line represents the growth rate of total Swiss exports to the world during the 2010-2019 period (60.4%) and the horizontal dotted line represents the growth rate of Peru's total imports from the world during the 2010-2019 period (41.2%).

The selection of products was subject to two conditions: i) the products imported by Peru from Switzerland, on average, have a value of more than more than US\$30.000 per year during the period 2010-2019 and ii) they must have been traded for at least five years.

These two conditions enable to select the Medtech products that are most relevant to trade between Peru and Switzerland. They are imported with some regularity and with a certain volume and may provide indications to Swiss SMEs to further develop the Peruvian market (26)³⁷.

³⁷ Five products have not been included in figure 4 because they would have required much larger scales, namely: Articles worn, carried, or implanted in the body, to compensate for a defect (HS 9021.90), Reagents for determining blood groups (HS 3006.20), Furniture for medical, veterinary use (HS 9402.90), Electro-diagnostic apparatus (HS 9018.19) and Dental fittings (HS 9021.29).

Figure 21. Medtech Business Opportunities, 2010-2019



Note: Horizontal axis (X-axis): Peru's imports from Switzerland.
 Vertical dotted line: average of Swiss export growth to the world 2010-19 (60.4%).
 Vertical axis (Y-axis): Peru's imports from the world.
 Horizontal dotted line: Average of Peru's imports growth from the world 2010-19 (41.4%).

Source: Comtrade, Peru trade data
 Elaboration: Swiss Chamber of Commerce in Peru (CCSP)

5.1.1. Strong market and strong Swiss response

This first quadrant comprises products recording a growth rate higher than the average Swiss growth to the world and higher than the average of Peru's imports from the world. It displays therefore products where Swiss exporters are exploiting opportunities in rapidly growing markets.

Switzerland is increasingly tapping into these Medtech products in Peru in the face of strong demand

We encounter 13 product groups out of a total of 26. In 2019, Peru's total imports of these products amounted to US\$220 million with imports from Switzerland of approximately US\$6.5 million with the data of the Swiss Customs and US\$7.3 million with COMTRADE Peru data. The discrepancy between both data sources is within an acceptable range. The size of the Peruvian imports is

illustrated with the blue bubbles (Peru's total Medtech imports from the world in 2019). It fluctuates between US\$1.2 million for reagents (HS 3006.20) and US\$95.7 million for instruments and appliances (HS 9018.90).

For four products, namely reagents (HS 3006.20), furniture for medical, surgical use (HS 9402.90), dental fittings (HS 9021.29) and articles worn or implanted in the body to compensate for a defect (HS 9021.90), Swiss products have a strong position; their performance is much higher than Peru's average imports³⁸. Noteworthy to point that Peru's market is particularly large for instruments. Swiss products fare also well for electrocardiographs (HS 9018.11), various needles (HS 9018.39, HS 9018.32) and X-ray tubes (HS 9022.30).

Table 4. Medtech with strong Swiss response, 2010-2019

Product Code	Description	Market size 2019 (US\$ millions)	Growth rates of Peru's imports from Switzerland	Imports from Switzerland 2019 (US\$ thousands)
9018.90	Instruments and appliances used in medical, surgical or veterinary sciences	95.69	186%	2702.4
9018.39	Needles, catheters, cannula and the like, used in medical sciences	43.17	329%	705
9018.31	Syringes, with or without needles, used in medical sciences	15.72	177%	193.6
9018.50	Ophthalmic instruments and appliances, n.e.s.	15.02	70%	968.1
9021.90	Articles and appliances, which are worn or carried, or implanted in the body, to compensate for a defect or disability	10.37	1184%	1007.1
9402.90	Furniture; for medical, surgical, veterinary use and parts thereof	8.76	5942%	60.8
9021.39	Artificial parts of the body (excl. those of orthopedic or fracture, artificial teeth and dental fittings, dental fittings and artificial joints)	8.40	93%	117.4
9018.32	Tubular metal needles and needles for sutures, used in medical sciences	6.78	398%	61.6
9021.31	Artificial joints for orthopedic purposes	6.13	213%	124.6
9022.30	X-ray tubes	4.84	266%	44.7
9021.29	Dental fittings (excl. artificial teeth)	2.96	3303%	437.4
9018.11	Electro-cardiographs	1.32	406%	78.1
3006.20	Reagents for determining blood groups or blood factors	1.23	7136%	752.5
TOTAL / AVERAGE		220.4	264.3%*	7256.3

Note: (*) Weighted trade average growth of Peru's imports from Switzerland 2010-19

Source: Comtrade

Elaboration: Swiss Chamber of Commerce in Peru (CCSP)

5.1.2. Strong market with moderate Swiss response

The second quadrant comprises some products recording a lower growth rate than the Swiss average to the world and some products with a decline but where Peru's imports from the world are higher than average. This implies that Swiss exports do not fully exploit opportunities.

The second quadrant comprises some products recording a lower growth rate than the Swiss average to the world and some products with a decline but where Peru's imports

³⁸ These products are not shown in figure 26 because their respective growth rates are so large (HS 3006.20: + 7136%; HS 9402.90: + 5942%; HS 9021.29: +3303%; HS 9021.90: +1184%) that they would not allow us to observe the results of the other products.

from the world are higher than average. This implies that Swiss exports do not fully exploit opportunities.

Switzerland is not taking full advantage of some of these products despite a growing import demand in Peru

It comprises 8 product categories. In 2019, Peru's total import market for these products amounted to US\$105 million with imports from Switzerland of approximately US\$6.3 million. The size of the Peruvian market or blue bubbles (total Medtech imports from Peru in 2019) fluctuates between US\$3 million for pacemakers (HS 9021.50) and US\$53.7 million for diagnostic or laboratory reagents (HS 3822). Noteworthy to point that the size of the Peruvian import market is particularly large for diagnostic reagents and orthopedic appliances.

Swiss products that have positive growth rates but not higher than the growth rate of Swiss exports to the world are dental cements and other dental fillings (HS 3006.40), diagnostic or laboratory reagents (HS 3822.00), orthopedic appliances (HS 9021.10) and hearing aids (HS 9021.40).

Four products, namely apparatus based on the use of X-rays (HS 9022.19), therapeutic respiration apparatus (HS 9019.20), pacemakers (HS 9021.50) and adhesive dressings (HS 3005.10) have a weak position; their performance (negative values) is much lower than Peru's average imports. Analyzing the reasons of the decline in Peru's imports from Switzerland for these products may provide clues on how to take advantage of a market in constant growth.

Results indicate that the performance of these products could be improved.

Table 5. Medtech with moderate Swiss response, 2010-2019

Product Code	Description	Market size 2019 (US\$ millions)	Growth rates of Peru's imports from Switzerland	imports** from Switzerland (US\$ thousands)
3822.00	Diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents, and certified reference materials	53.7	38%	354.6
9021.10	Orthopedic or fracture appliances	16.0	36%	3847.7
3005.10	Adhesive dressings and other articles having an adhesive layer for medical, surgical, dental or veterinary purposes	8.0	-13%	22.3
9022.19	Apparatus based on the use of X-rays (other than for medical, surgical, dental or veterinary uses)	7.5	-64%	191.9
9019.20	Ozone therapy, oxygen therapy, aerosol therapy, artificial respiration or other therapeutic respiration apparatus	7.3	-54%	432.2
3006.40	Dental cements and other dental fillings; bone reconstruction cements	6.7	52%	549.6
9021.40	Hearing aids (excl. parts and accessories)	3.4	26%	452.4
9021.50	Pacemakers for stimulating heart muscles (excl. parts and accessories)	3.0	-47%	439.5
TOTAL / AVERAGE		105.6	2.5%*	6290.2

Note: (*) Weighted trade average growth of Peru's imports from Switzerland 2010-19

(**) Volume of Peru's imports from Switzerland in 2019

Source: Comtrade

Elaboration: Swiss Chamber of Commerce in Peru (CCSP)

5.1.3. Lower than average growth

The third quadrant comprises products recording a growth rate lower than the average Swiss growth to the world and lower than Peru's average imports from the world. This implies that Peru's import growth is not as dynamic as for other products.

This quadrant comprises only disinfectants (HS 3808.94) and artificial teeth (HS 9021.21) with total Peruvian imports (blue bubbles) of respectively US\$12.2 million and US\$1.1 million; imports from Switzerland amounted to US\$0.014 million. Imports of Swiss artificial teeth ranged between US\$81060 (2011) and US\$162914 (2013). Comtrade data provides a decline of 1% between 2010 and 2014 and then no more imports from Switzerland. On the other hand, according to Swiss trade statistics, Switzerland exported artificial teeth to Peru also in subsequent years (2018: SFR 192 864; 2019: SFR 171 594). The data difference may result from product classification divergence between Swiss and Peruvian customs. It may be pointed that the largest Swiss producer, Straumann, manufactures in Switzerland high-end products and in Brazil less expensive ones for the world market.

Trade in Medtech products faces a situation where both supply and demand are on a lower growth path

Referring to disinfectants, Switzerland has no comparative advantage in terms of price competitiveness and technology. Nevertheless, Peru's imports from Switzerland increased very significantly in 2020 to meet domestic health needs under the Covid crisis (See figure 23).

Table 6. Medtech Products with lower than average growth, 2010-2019

Product Code	Description	Market size 2019 (US\$ millions)	Growth rates of Peru's imports from Switzerland	Imports from Switzerland 2019 (US\$ thousands)
3808.94	Disinfectants and similar products, put up for retail sale or as preparations or articles	12.2	-87%	14
9021.21	Artificial teeth	1.1	-1%	-
TOTAL / AVERAGE		13.3	-87%*	14

Note: (*) Weighted trade average growth of Peru's imports from Switzerland 2010-19

Source: Comtrade

Elaboration: Swiss Chamber of Commerce in Peru (CCSP)

5.1.4. Good Swiss performance in a low growth market

The fourth quadrant comprises products recording a growth rate higher than the average Swiss growth to the world and where Peru's average imports from the world is lower than average. This implies that Swiss exports face a local market with a lower growth rate.

This quadrant comprises three products, namely electro-diagnostic apparatus (HS 9018.19)³⁹, instruments used in dental sciences (HS 9018.49) and X-ray generators (HS 9022.90). In 2019, Peru's total import market for these products amounted to \$32.6 million with imports from Switzerland of approximately US\$1.8 million.

In the face of lower import demand than average from Peru, Swiss exports are growing strongly

Noteworthy to point that the products of this group have a high technological level and reflect Swiss specialization and comparative advantage. The progressive increase of income per capita and living standards in Peru over the coming years should contribute to strengthen market opportunities for Swiss firms.

Table 7. Medtech products with good Swiss performance in a low growth market, 2010-2019

Product Code	Description	Market size 2019 (US\$ millions)	Growth rates of Peru's imports from Switzerland	Imports from Switzerland 2019 (US\$ thousands)
9018.19	Electro-diagnostic apparatus, incl. apparatus for functional exploratory examination or for checking physiological parameters	13.5	32202%	493.9
9018.49	Instruments and appliances used in dental sciences, n.e.s.	9.9	66%	1314.7
9022.90	X-ray generators other than X-ray tubes, high tension generators, control panels and desks, screens, examination tables, chairs.	9.2	228%	28.9
TOTAL / AVERAGE		32.6	129%*	1837.5

Note: (*) Weighted trade average growth of Peru's imports from Switzerland 2010-19

(**) Volume of Peru's imports from Switzerland in 2019

Source: Comtrade. Elaboration: Swiss Chamber of Commerce in Peru (CCSP)

³⁹ This product is not shown in figure 26 because its growth rates is so large (32202%) and it would not allow observing the data of the other products.

5.1.5. Additional business opportunities

Table 10 groups 15 Medtech products that Peru does not import from Switzerland.

It is important to note that Switzerland exported approximately only US\$133 million dollars⁴⁰ in these products to the world in 2019, a small volume compared to Swiss total Medtech exports of US\$13.1 billion.

The main destination was Europe. In the future, Peru could also eventually be considered by some Swiss firms producing the technologically most advanced products.

Switzerland, not present on the markets for these products, is not taking advantage of them. Consequently, Switzerland could consider entering these markets and benefit from growing demand in Peru

Table 8. New Business opportunities, 2010-2019

Product Code	Description	Market size 2019 (US\$ millions)
3401.11	Soap and organic surface-active products and preparations, impregnated or covered with soap or detergent, for toilet use, incl. medicated products	36.8
9018.12	Ultrasonic scanning apparatus	19.1
9020.00	Breathing appliances and gas masks	15.3
4015.11	Surgical gloves, of vulcanized rubber	15.1
3006.30	Opacifying preparations for X-ray examinations; diagnostic reagents designed to be administered to the patient	11.3
4014.10	Sheath contraceptives of vulcanized rubber	6.2
9022.13	Apparatus based on the use of X-rays for dental uses (exc. computer tomography apparatus)	2.8
7018.20	Glass microspheres not >1mm in diameter	2.5
9001.30	Contact lenses	2.2
9001.40	Spectacle lenses of glass optically worked	2.0
9018.20	Ultraviolet or infra-red ray apparatus used in medical sciences	1.5
3306.20	Yarn used to clean between the teeth "dental floss", in individual retail packages	0.8
9022.29	Apparatus based on the use of alpha, beta or gamma radiations (other than for medical, surgical, dental or veterinary uses)	0.6
9022.21	Apparatus based on the use of alpha, beta or gamma radiations, for medical, surgical, dental or veterinary uses	0.6
9018.14	Scintigraphic apparatus	0.5
TOTAL		117.3

Source: Comtrade
Elaboration: Swiss Chamber of Commerce in Peru (CCSP)

⁴⁰ Swissimpex data

5.2. Challenges to do business in Peru



Peru offers a framework for trade and investment characterized by administrative procedures often somewhat complex. According to the World Bank's 2020 "Doing Business" report⁴¹ Peru is ranked 76th overall. Economic actors face significant challenges in doing business in Peru.

- Starting a business is a bureaucratic process (133th rank). It takes around 24 days and eight procedures to set up a business. The heaviest procedures are the deed of incorporation before a notary public and file it online with the Public Registry (SUNARP), which takes 8 days, and obtaining a technical inspection of building safety (ITSE) and the operating license (15 days). If the shareholders are from abroad, the incorporation process usually takes much more time.
- Doing Business report ranks Peru 121st for paying taxes. It involves eight payments per year and 260 hours. Profit (22.7%) and labour (11%) taxes are the main ones, with corporate tax at 29.5%. VAT (Value added tax) is added to most goods for sale, particularly imported items. The rate is 18%; imported goods may then turn out to be quite expensive.
- Trading across borders is a slow and expensive process (102th rank). The time required for border compliance is 72 hours with a cost of US\$700 and 48 hours with a cost of 80 dollars for documentary compliance.

“Having a sanitary registration for a product does not yet mean that you are going to sell. There is a specific registration process if you want to sell to the State, there is a process for EsSalud and MINSA, and there is another one for the Armed Forces. There are several barriers to overcome. The whole process is not quick, it may take 3, hopefully 2 and a half or 2 years”
Lima Chamber of Commerce Health Association

Macroeconomic soundness is one of Peru's strength with a rigorous monetary and fiscal policy over many years. This has contributed to achieving one of the highest growth rates in Latin America during the past decade. However, the current political situation, characterized, among other things, by constant changes of ministers, has generated uncertainty for business. This political landscape embodies risks that may discourage investment and business, slowing down the growth of the economy.

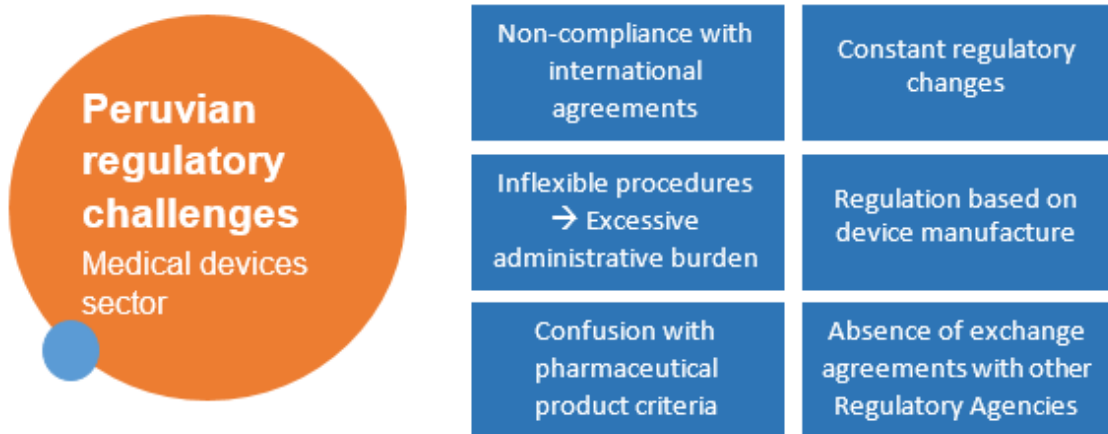
In Peru, corruption is a very big issue. The most famous case involves a large Brazilian construction company, which admitted paying bribes in various countries in Latin America, including Peru. Peruvian legislation recognizes the corporate criminal liability applicable to bribes, so companies need to maintain open, honest and compliant business practices which are fully transparent with the law.

⁴¹ Doing Business 2020 is the 17th in a series of annual studies investigating the regulations that enhance business activity and those that constrain it. Doing Business presents quantitative indicators on business regulations and the protection of property rights that can be compared across 190 economies. Available on line: <https://espanol.doingbusiness.org/content/dam/doingBusiness/country/p/peru/PER.pdf>

Foreign firms are being forced to forego important business opportunities because they refuse to make illicit payments to officials of public institutions

Regulation also raises significant issues for exporters of medical devices as illustrated in Figure 27. According to Mrs Cindy Vásquez Vargas from South LATAM- Medtronic⁴², the challenges faced by Peruvian regulation in the medical device sector have to do with non-compliance with international agreements; the inflexibility of procedures is also a limitation, as well as a high administrative burden, which can lead to delays in the import process. The constant regulatory changes generate an unpredictable market; for example, supreme decree No. 016-2011-SA- Regulation was modified at least 11 times between 2012 and 2020. Finally, the absence of agreements with other regulatory agencies limits the exchange of information and collaboration, especially with the United States and the European Union.

Figure 22. Challenges of Peruvian regulation



* Resources, training and institutional framework
Source: Regulatory Quality in Peru, Progress and Future Agenda (2021)

⁴² Available on line: www.interamericancoalition-medtech.org/regulatory-convergence/wp-content/uploads/sites/4/2021/09/Desafios-y-oportunidades-de-la-Convergencia-Regulatoria-en-el-Peru-Cindy-Vasquez.pdf

6. IMPORTANT MARKET PLAYERS

In 2019, more than 3000 companies imported Medtech products in Peru, the three largest accounting for US\$54 million. The major competitors of Swiss firms were China, the United States and Germany (US\$305 million). On a product basis, Switzerland ranked in the top 3 suppliers for seven Medtech devices and in the top 5 for 14. Private clinics and hospitals managed by regional governments represent 94% of the infrastructure in the health sector. They are all important partners for Swiss exporters.



Among the actors active in Peru's Medtech market, this chapter will focus on the main importers, the major supplying countries and establishments providing health services.

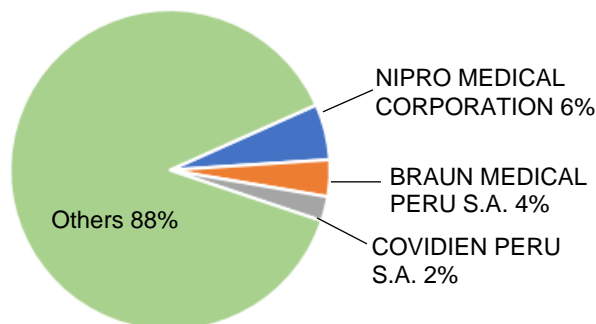
6.1. Distributors: Main Importing Companies

In 2019, approximately 3,000 companies imported Medtech products in Peru. The highest imported value was registered by 3M PERU SA (US\$23.3 million) followed by OPTICAS GMO PERU S.A.C (US\$17.7 million) and NIPRO MEDICAL CORPORATION SUCURSAL DEL PERU (US\$13 million).

The product categories with the highest number of importing companies were orthopedic appliances (HS 9021) with 300 companies; mechanic-therapy appliances (HS 9019) with 326 companies; diagnostic reagents (HS 3822.00) with 536 companies; spectacles, goggles and the like (HS 9004) with 692 companies and instruments used in medical, dental sciences (HS 9018) with 785 companies⁴³.

Figures 28-30 present the three products with the highest level of imports in 2019 with the main domestic importers.

Figure 23. Main importers of instruments and appliances (HS 9018)



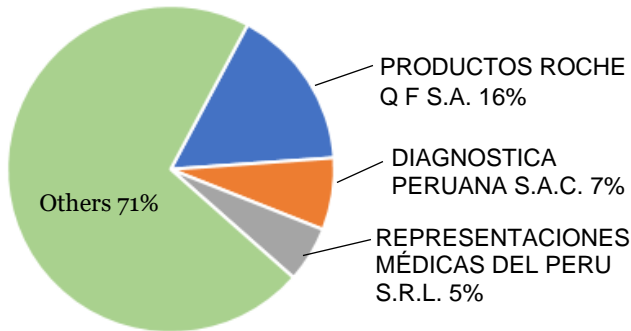
HS 9018: Instruments and appliances used in medical, surgical, dental or veterinary sciences, incl. scintigraphic apparatus, other electro-medical apparatus and sight-testing instruments.

Source: ADEX Data Trade platform
Elaboration: Swiss Chamber of Commerce in Peru (CCSP)

For these products, there is a very large number of importers for a total value US\$231.5 million in 2019.

⁴³ Source: ADEX Data Trade platform

Figure 24. Main importers of diagnostic or laboratory reagents (HS 3822)



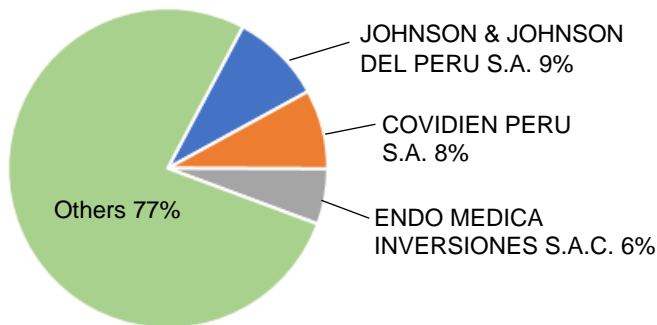
HS 3822: Diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, and certified reference materials.

Source: ADEX Data Trade platform

Elaboration: Swiss Chamber of Commerce in Peru (CCSP)

The imported value in 2019 was US\$53.6 million. Roche Q F S.A. also imports products from other countries (Germany, Japan, United States, Brazil, China, etc.) so that its imports do not come exclusively from Switzerland.

Figure 25. Main importers of orthopedic appliances (HS 9021)



HS 9021: Orthopedic appliances, including crutches, surgical belts and trusses; splints and other fracture appliances; artificial parts of the body; hearing aids and other appliances which are worn or carried, or implanted in the body, to compensate for a defect or disability.

Source: ADEX Data Trade platform

Elaboration: Swiss Chamber of Commerce in Peru (CCSP)

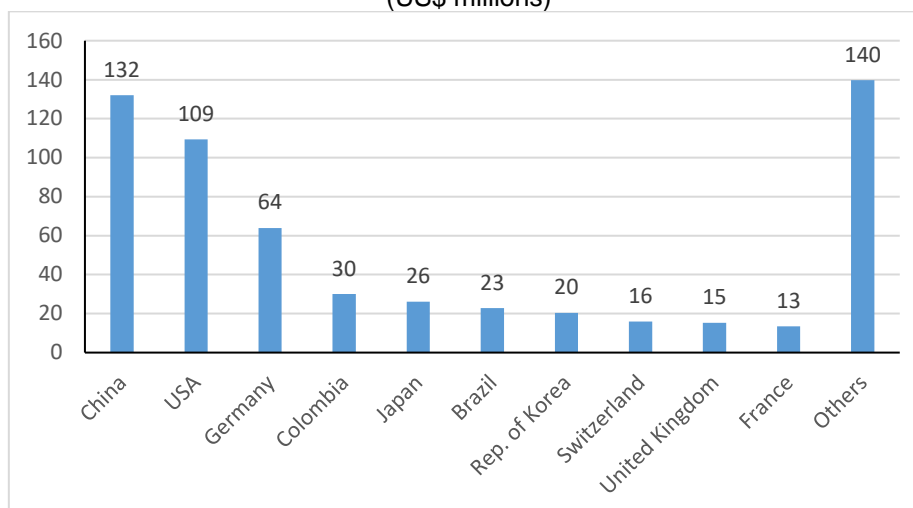
In 2019 the imported value for orthopedic appliances was \$51.4 million.

6.2. Suppliers: Main Competitors by Countries

Switzerland's three main competitors in the Peruvian market for Medtech products are: first, China, from which Peru imported 57 different types of products (out of a total of 60 products analyzed in this study) for a value of US\$132 million. Second, the United States with 55 products and a value of US\$109 million and third Germany with 52 products for US\$64 million. Peru imported 43 products from Brazil, 42 from Spain, and 41 each from the Republic of Korea, Italy and Mexico respectively. Finally, 39 products were imported from Japan and 38 from the United Kingdom.



Figure 26. Main countries supplying Medtech products to Peru, 2019
(US\$ millions)



Source: Comtrade

Elaboration: Swiss Chamber of Commerce in Peru (CCSP)

In 2019, Switzerland ranked eighth (out of 87 countries). Out of the 33 products, Swiss three best ranking and key competitors were:

1. Orthopedic or fracture appliances (HS 9021.10) with a value of US\$3.8 million, and first place among Peru's suppliers, ahead of China and the United States.
2. Medical, surgical or dental instruments (HS 9018.90) with a total of US\$2.7 million and an eighth place out of a total of 61 supplying countries.
3. Instruments used in dental sciences (HS 9018.49), with a value of US\$1.3 million with a second rank out of a total of 32 countries behind China and ahead of Germany.

Some other positions with a lower import value also deserve to be highlighted:

- Reagents for the determination of blood groups (HS 3006.20) with a value of US\$0.753 million and a first rank ahead of Spain and the United States.
- Mechano-therapy apparatus (HS 9019.10) with a value of US\$0.568 million and a second place after China and ahead of the Republic of Korea.
- Articles worn or implanted in the body to compensate for a defect (HS 9021.90) with a value of US\$1 million and a third rank, after the United States and Ireland.
- Hearing aids (HS 9021.40) with a value of US\$0.452 million and a third place after Denmark and Singapore.

Finally, Switzerland does not have a good market position for the following products:

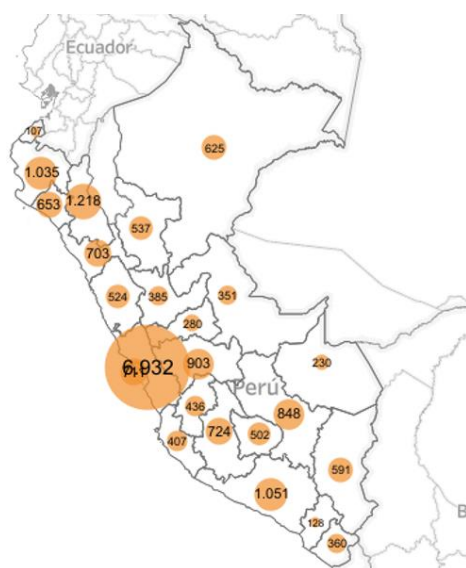
- Dressings and other articles with adhesive coating for medical, surgical, dental or veterinary uses (HS 3005.10) with a value of US\$22300, 16th rank (out of 25 countries).
- Disinfectants (HS 3808.94) with a value of US\$14000, 23rd rank (out of 27 countries).
- Spectacle lenses (HS 9001.50), with a value of US\$6100, 14th rank (out of 18 countries).
- Apparatus based on the use of X-rays for medical purposes (HS 9022.14), with a value of US\$1500, 15th position (last place).

6.3. Health sector establishments

Health facilities (public and private hospitals, private clinics, dental centers, etc.) play a key role in the demand for medical products. This section will showcase the availability of health facilities in the Peruvian territory, differentiating them according to their category and type of provider.

- a) Figure 32 shows that health facilities are concentrated in Lima and Metropolitan Lima. It should be noted that the population of Lima represents almost one-third of Peru's, hence the high number of health facilities in that city.

Figure 27. Peru - Health facilities, by Department



Note: Information updated to January 2021

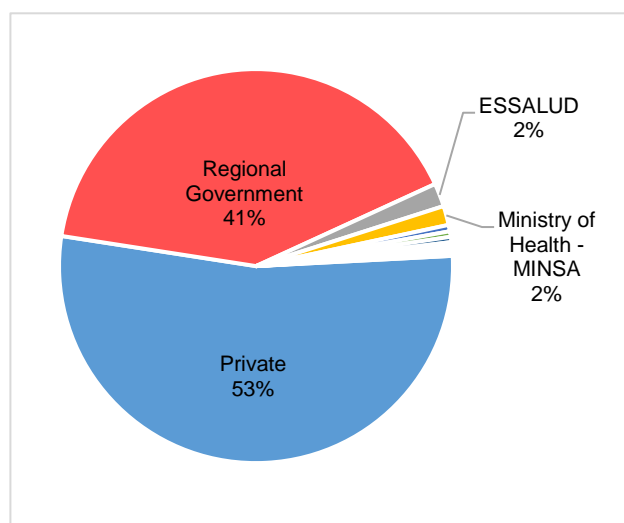
Source: National Superintendence of Health (SUSALUD). National Registry of Health Service Providers (RENIPRESS).

Available on line: <http://siaperu.paho.org/SIA/index.php/sala-de-situacion#/categorie/21/sistemas-de-salud>

- b) Figure 33 presents the availability of health establishments according to the type of service provider. Private clinics and hospitals managed by regional governments represent 94% of the infrastructure in the health sector. Private clinics generally access medical devices through importing companies while the Peruvian state and its institutions proceed with public bidding processes.

Figure 28. Peru - Health establishments, by type of Provider

Institution	Total
Private	11265
Regional Government	8608
ESSALUD	404
Ministry of Health - MINSA	333
Army	111
Other	95
Peruvian National Police - PNP	91
Navy	57
National Penitentiary Institute - INPE	55
Provincial Municipality	51
District Municipality	37
Peruvian Air Force - FAP	36



Note: Information updated to January 2021

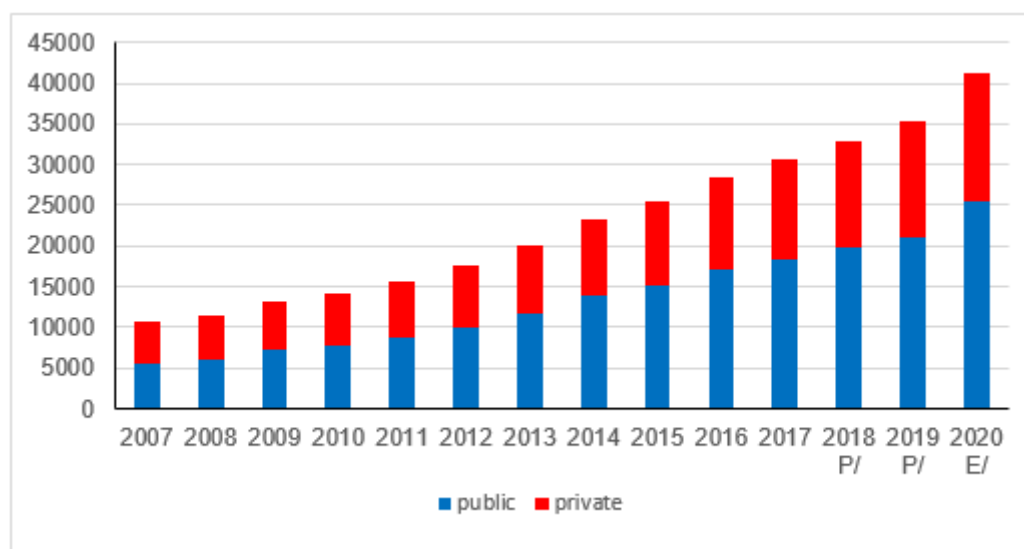
Source: National Superintendence of Health (SUSALUD).

National Registry of Health Service Providers (RENIPRESS).

Available on line: <http://siaperu.paho.org/SIA/index.php/sala-de-situacion#/categorie/21/sistemas-de-salud>

- c) Figure 34 shows that health sector spending has been growing very strongly since 2007 (2007-2017: + 233%). This implies that spending for medical devices has also grown significantly. While public and private spending were practically the same in 2007, the gap has widened by about 10 billion soles. According to preliminary data, public spending represented 59% and private spending 41% in 2019.

Figure 29. Expenditure allocated to the health sector, 2007 - 2020
(soles millions)⁴⁴



Note: Private health expenditure corresponds to the Gross Value of Production of the private health activity (not including EsSalud).

Source: National Institute of Statistics and Informatics (INEI)

Available on line: www.inei.gob.pe/estadisticas/indice-tematico/health

⁴⁴ Exchange rate: 1US\$ = 3.86 sol, 14.01.22. Source: [dollar value in lima peru - Bing](#)

According to the Report on the Quality of Public Health Spending⁴⁵, from COMEXPERU, a total of S/. 956 million was allocated in 2019 for materials, supplies and instruments necessary for health care, of which only 87.6% was spent. At the departmental level, Huancavelica and Loreto stand out with 97.7% and 97.4%, while San Martín and Callao only executed 71.4% and 73.3% of their budget, respectively.

⁴⁵ Available on line: www.comexperu.org.pe/upload/articles/reportes/informe-calidad-001.pdf

7. LOGISTICS AND DISTRIBUTION

In order to transport, deliver and ensure the quality and integrity of medical devices, establishments engaged in the manufacture, import, distribution, storage and dispensing of such products must comply with basic sanitary conditions, and also with DIGEMID's sectorial regulations. They establish the minimum mandatory standards for the distribution and transport of pharmaceutical products and medical devices nationwide. Market entry can be undertaken under various forms.



Imports in the Medtech sector have been growing in recent years. As a result of the Covid-19 pandemic, their need has become more relevant and it is expected that budgets will increase in the future. For some imports, it is important to consider the cold chain to be maintained⁴⁶

Establishments engaged in the manufacture, import, distribution, storage and dispensing of pharmaceuticals and medical devices must comply with sanitary conditions and the Manual of Good Distribution and Transportation Practices ⁴⁷ (established by the General Directorate of Medicines - DIGEMID in 2018), among others, to ensure the maintenance of the quality, integrity, characteristics and optimal conditions of these products during transportation.

This Manual establishes a set of mandatory minimum standards for the distribution and transport of pharmaceuticals and medical devices at the national level. It is mandatory for drugstores and specialized warehouses requiring strict controls by the sector and new transport standards⁴⁸.

This was necessary to ensure that the products are distributed, transported and handled under appropriate conditions according to the specifications established by the manufacturer to preserve their quality, efficacy and safety. The key points below refer to pharmaceuticals, medical devices and sanitary products under the terms "medical products".

Quality assurance system

- Companies that distribute and transport medical products should have both a quality policy and guidelines that must be approved by the relevant authorities at a high level.
- Quality assurance should ensure that medical products are of the quality required for their intended use, ensuring that: all operations, roles and responsibilities of the personnel are clearly specified and the provisions contained in the Good Distribution and Transport Practices are adopted. The necessary procedures need to be established and implemented to ensure that medical products are handled, stored, distributed and transported so that their quality is maintained throughout their shelf life. Self-inspection procedures need to be established and applied to periodically evaluate the applicability and effectiveness of the Good Distribution and Transport Practices manual (at least once a year, or whenever

⁴⁶ Nikolai Balarin Guerinoni - Head of Supply Chain (Roche Products Q.F.S.A.)

⁴⁷ Issued by the Ministry of Health through Ministerial Resolution No. 083-2015/MINSA. Available on line: www.digemid.minsa.gob.pe/UpLoad/UpLoaded/PDF/Publicaciones/DocumentosVarios/P32_2015-12-29_RM_833_2015.PDF (Accessed on 01/11/21)

⁴⁸ Nikolai Balarin Guerinoni - Head of Supply Chain (Roche Products Q.F.S.A.)

any deficiency or need for corrective action is detected). Complaints, claims, deviations, returns and recalls have to be reported, investigated and recorded; and, have a procedure for handling corrective and preventive actions. Establishments must have a Quality Manual that demonstrates the commitment of their organization management in order to comply with the quality assurance system.

Personnel

- Manufacturers of medical products should have the required number of personnel with the necessary qualifications and experience for the functions to perform. Management and technical personnel shall have the necessary resources, information and training to carry out their functions.
- The Technical Manager is responsible to comply with and enforce compliance with Good Distribution and Transportation Practices. All personnel involved in the distribution and transport must comply with defined roles and responsibilities. They should receive an introduction to operating procedures and ongoing training according to a documented program.
- In working areas where medical products are handled, personnel should wear appropriate uniforms and safety gear according to the type of work performed.

“The sales representatives make the presentations to the doctors. There are other forms of training such as monthly lectures in hospitals. As for the equipment, there are introductions to learn how to use them. Nowadays there are webinars, virtual training, videos, internal chats between doctors and companies.”

*Lima Chamber of Commerce
Health Association*

Facilities and equipment

- Establishments involved in distribution and transport of medical products must have the appropriate infrastructure and equipment to ensure the conservation of the quality of the products, taking into consideration the specific storage needs, according to the nature of the product and other requirements. These facilities should comply with the requirements established in the Good Storage Practices Manual.
- The location, construction, adaptation and maintenance of the areas used for reception, storage and dispatch processes should be appropriate for all the operations carried out, and should be kept clean, free of contaminating substances or materials. The maneuvering yard, loading and/or unloading area for the use of transport vehicles should be clean and free of pests.
- Climate control equipment inside the vehicle or validated packaging material that ensures conservation of the required temperature for the distribution and transport should be considered for products that require them. In the transport vehicle, temperature control equipment should be calibrated and the performance of the transport process should be qualified. The distribution and transport that require a cold chain should consider air-conditioned vehicles or qualified packaging.

Packaging and Dispatch

- Medical products should be packaged and dispatched according with the provisions of the Good Storage Practices Manual and other applicable standards.
- Depending on the nature of the products, the minimum protection against routine environmental and physical hazards should be considered, evaluating performance factors of the packaging exposed to vibration, shock and protecting the content from any impact and displacement.
- Manufacturers should design protective packaging according to environmental factors, means of transport and transport time, depending on the nature of the product, medical device and sanitary product.

Distribution and transport

- Distribution should take place in vehicles with facilities that do not affect the quality of the products and which offer adequate protection from external influences and should be distributed and transported in accordance with procedures that allow the identification of the packaging. Products should not contaminate and be not contaminated by other products. Due precautions should be taken against breakage, spills, confusion and theft.
- The distribution systems selected for delivery should take into account basic operational parameters with schedules and route planning. The date and time of receipt should be recorded as well as the temperature and humidity (when applicable).
- Medical products which contain hazardous substances need to be transported in separate containers or packaging, properly designed and in safe and in protected vehicles for transport.
- Pharmaceutical establishments should have procedures for rejected, expired, returned, recalled, controlled products and those suspected of originating from illegal trade. These medical products, when transported, must be properly packaged, identified and have the corresponding documentation.
- If any deviation from the established conditions by the manufacturer occurs during distribution or transport, it should be evaluated and the items should be segregated. There should be a procedure in order to take action.
- The personnel providing the transport service must provide the corresponding documentation to the client, such as invoice, bill of lading or air and road waybill, among others, as appropriate. Personnel providing the transport service should have adequate equipment and instructions to resolve unforeseen situations and be trained for this purpose. Transport vehicles must have security mechanisms to prevent theft and misappropriation of products. If such events occur, it has to be reported to the Peruvian National Police, the pharmaceutical establishment, the transport service party and the Health Authority of the jurisdiction.
- When arriving at the pharmaceutical establishment, products should be the first to be transferred to the corresponding warehouse area.

Single Window for Foreign Trade - VUCE⁴⁹

It is important to mention that Peru has a Single Window for Foreign Trade - VUCE, a system that streamlines foreign trade by allowing, through electronic means, the parties involved in foreign trade and international transport to exchange the required or relevant information for the entry, exit or transit of goods and means of transport to or from the national territory. In addition, it enables users to manage documentation and information

⁴⁹ Available on line: www.vuce.gob.pe (Accessed on 01/11/21)

regarding procedures and services related to foreign trade that are processed through the system.

The Single Window for Foreign Trade has the following objectives:

- Integrate and improve processes by simplifying and standardizing procedures, forms and deadlines.
- Channel the information required and provided by the entities through electronic means, in order to ease foreign trade.
- Facilitate, coordinate and ensure that the exchange of information is electronic and free of charge among the competent entities.
- Provide legal security through the provision of accurate and binding information to the parties involved.

7.1. Company structures for distribution

In order to distribute its products in Peru, an exporter has several options. He can seek a local distributor or establish one. The General Law of Companies⁵⁰ outlines the different types of companies and the requirements for their creation. The main aspects of these types are mentioned hereunder according to Ernst & Young⁵¹:

a. Joint Stock Companies

These companies require a minimum of two shareholders. The non-domiciled shareholders must designate an attorney in Peru to sign off on the bylaws. The funds must be deposited in a local bank and can be in local or foreign currency for the initial capital contribution (there is no minimum amount required but financial institutions generally require PEN 1,000 - approximately US\$300). The capital stock is represented by shares, which are represented by certificates or book entries in return. The Trade Name must include “Sociedad Anónima” or the abbreviation “S.A.” and, Shareholders' liability is limited to the shares they hold and partners are not personally liable for the corporate debts.

b. Closely Held Corporations

These corporations resemble limited liability companies. They must have between two and twenty shareholders. Shares cannot be listed on the Public Stock Exchange Registry (RPMV) of the Peruvian Securities and Exchange Superintendency (SMV). The corporate name must include “Sociedad Anónima Cerrada” or the abbreviation S.A.C. Shareholders' liability is limited to the shares they hold, and partners are not personally liable for the corporate debts.

c. Publicly Held Corporations

Publicly held corporations are intended to be companies with a large number of shareholders (more than 750), for which debts can be converted into shares, an Initial Public Offering has been made, or more than 35% of the capital stock belongs to 175 or more shareholders. These shares must be listed on the Public Stock Exchange Registry (RPMV) of the Peruvian Securities and Exchange Superintendency (SMV). These corporations must include the indication “Sociedad Anónima Abierta” or the abbreviation S.A.A. Shareholders' liability is limited to the shares they hold. Partners are not

⁵⁰ Available on line: <https://diariooficial.elperuano.pe/pdf/0004/2-ley-general-de-sociedades-1.pdf> (Accessed on 09/11/21)

⁵¹ Available on line: www.ey.com/es_pe/entrepreneurship/peru-business-investment-guide (Accessed on 09/11/21)

personally liable for the corporate debts. These companies are subject to the supervision of the Peruvian Securities and Exchange Superintendency (SMV), and the transfer of shares is completely free (no restrictions or limitations are permitted).

d. Limited Liability Companies

These companies are established with a minimum of two and a maximum of twenty partners. This type of company will not issue shares. The incorporation procedures will be the same as those for the other corporations. Its capital is divided into ownership interests, which are accumulative and not divisible. Its name must include "Sociedad Comercial de Responsabilidad Limitada" or the abbreviation "S.R.L." and partners are not personally liable for the corporate obligations.

e. Branches

Branches, either national or foreign, carry out activities in different location than its principal place of business. They do not have their own separate legal standing. The parent company is liable for the branch's obligations. For branches established by foreign corporations, the agreement for the establishment of a branch by the parent company need to be notarized by the Peruvian consulate and certified by the Ministry of Foreign Affairs (MRE) in Peru, or be apostilled in its country of origin for it to be put into the form of a notarially recorded instrument and registered in the Public Records Office. Branch registration requires, among other things, a certificate of good standing of the parent company, duly notarized or apostilled, as applicable. According to the General Law of Companies, branches of foreign companies may be transformed so as to be incorporated in Peru under any corporation type regulated by the General Law of Companies.

8. CASE STUDIES

Testimonials from important firms -Roche, PANADEx- and medical groups - Association of Private Clinics of Peru, Health Association- illustrate key points of the report. Some issues and regulatory requirements are highlighted. The adoption of international standards and differences between the private and public sectors are also addressed. Opportunities are identified with health insurance programs which may represent the most promising market for exporting companies.

The objective of this chapter is to present concrete cases of companies or users of medical devices. This allows to experience their reality highlighting opportunities and challenges in importing, registering, putting on the market and commercializing such products.

To this aim, the Health Association (COMSALUD) of the Lima Chamber of Commerce was interviewed and questionnaires were sent to twenty importers and users including the Association of Private Clinics of Peru (ACP), Roche Q.F.S.A. and the PANADEx Group.

They all play an important role in Peru's Medtech sector. COMSALUD and ACP represent several companies and health institutions. On the other hand, Roche and PANADEx Group have a strong presence in in-vitro diagnostics and hearing aids, respectively.



The Association of Private Clinics of Peru (ACP)⁵² is an institution with a strong commitment to health and the companies that provide medical and health services. It is both a means of discussion of the technological advances of the sector, a support for debate on current medical news in the country, and a powerful union for the negotiation of the best conditions and the best environment for the health sector.

It is the most important business association of private health care establishments, with recognition from the main national and international authorities and is recognized as official spokesman of the Peruvian private health care sector.

Its philosophy can be summarized as the search for the articulation and unity of the private health services system with the highest quality criteria. This is achieved through the consolidation of those basic principles that govern them, such as professional excellence, technological innovation, healthy competition in a free market framework, and the highest quality in the service provided.

The ACP has more than 85 member entities nationwide.

⁵² Available on line: <https://acp.org.pe/>

According to the representative of the ACP, there are few domestic manufacturers of Medtech products. They only produce devices with limited technology such as beds and medical furniture. The lack of a Medtech industry implies that products must come from abroad; in the case of the ACP, mainly from China, the United States and Germany.

The registration and authorization's systems required to import and market Medtech products are very bureaucratic. Registration of a product can take up to 6 months, and DIGEMID requires it for each equipment. DIGEMID does not recognize automatically FDA (Food and Drug Administration) and EMA (European Medicines Agency) authorizations, although they could simplify administrative procedures.

The network of clinics with health insurance programs may represent the most promising market for exporting companies. Some insurance schemes are AUNA⁵³, Pacifico⁵⁴, Sanna⁵⁵, Rimac⁵⁶, Clinica Internacional⁵⁷ and Grupo San Pablo⁵⁸. Some of these groups have registered Droguerías qualified to import medical equipment.



The Lima Chamber of Commerce (CCL) is the main business association in Peru. It seeks to promote the development of free enterprise by enforcing its legitimate rights, facilitating business opportunities, providing assistance and services and boosting its competitiveness.

The CCL has more than 15,000 registered companies from the trade, production and services sectors, which represent 41.1% of Peru's exports and 52.3% of imports. It also has 15 Associations and 12 Commissions that bring together companies according to their activities.

According to the Health Association (COMSALUD)⁵⁹ of the Lima Chamber of Commerce, approximately 95% of medical devices are imported and only 5% are manufactured domestically. Sutures, gauze, syringes, catheters, disinfectants, orthopedics (limb replacement) are produced locally. Other Medtech products are imported because technology is not sufficiently advanced in Peru.

Most of the products come from China, the United States and India, especially from China, due to their low price. In Peru, purchases are made through tenders on the basis of price in particular for products such as syringes, silicone tubes and all the daily-use items that make up 70% of hospitals' needs. When it comes to equipment, purchases of quality brands are expensive.

⁵³ Available on line: <https://auna.org.pe>

⁵⁴ Available on line: www.pacifico.com.pe/

⁵⁵ Available on line: <https://sanna.es/es/>

⁵⁶ Available on line: www.rimac.com/

⁵⁷ Available on line: www.clinicainternacional.com.pe/

⁵⁸ Available on line: www.sanpablosalud.com.pe/red-de-salud/

⁵⁹ Available on line: www.camaralima.org.pe/lista-de-gremios

In terms of government certifications, licenses, standards and regulations, the supreme decrees DS-014 and DS-016 and their amendments regulate all Medtech devices. DIGEMID classifies Medtech products but not all products fit into its classification; there is a legal void. Initially only for pharma, standards apply now also to devices, natural products and equipment. DIGEMID has also issued a list for products that do not require a registration. According to DIGEMID, ISO 13485, US Food and Drug Administration (FDA) and European Union certificates are equivalent to good manufacturing practices.

Certifications from the 20 high surveillance countries (including Switzerland) are recognized in Peru, but there is no automatic recognition; all documentation must be submitted and authorization must be obtained for each product.

Training is provided several ways. For instance, sales representatives make the presentations to doctors, doctors train themselves and monthly lectures are usually held in hospitals. Companies also invite doctors to training sessions in congresses, to lectures and presentations. Training is not regulated. Nowadays, there are also webinars, virtual training, videos and internal chats between doctors and companies.

There is no difference between public social security systems in terms of the use of Medtech products in health insurance (SIS, IAFAS, the Armed Forces). Social security pays for all the needs of the patient. However, private insurers audit what the patient uses. For example, if one uses a product that is not covered by the insurance policy, the private insurers will not pay for it.

Regarding opportunities, there is always potential for medical devices. The private market is unfortunately much smaller than the public one, and can also be informal.

For instance, if someone presents to the public system the advantages of a new device representing a large investment such as a tomograph, it may be considered. Chinese or Indian products would not be considered.

A study would have to analyse various competing products.

A sanitary registration for a product is only a first step that does not guarantee a sale. There is a specific registration process if you want to sell to the State, another one for EsSalud, MINSA, and the Armed Forces. There are several barriers to overcome. The whole process is not quick, it may take three, hopefully two and a half or two years.

It is important to select well the product to be introduced in Peru, to be able to register it according to Peru's legal conditions, to have a strategic commercial partner to present the properties and advantages of the product to the clinics and hospitals, and who knows the different procedures of each institution.

A product, just by the fact that it is from Switzerland, is already an endorsement since Swiss products are accurate and precise.

Finally, if a Swiss company wants to export Medtech products to Peru it needs a drugstore in Peru. No direct purchases are made. It either needs to establish its own drugstore to register the product, or hire a representative which must be a drugstore with a warehouse registered.



Roche is the world's largest biotech company. It covers the following areas: oncology, neuroscience, infectious diseases, immunology, cardiovascular and metabolism, ophthalmology and respiratory.

Headquartered in Basel, Switzerland, Roche has made substantial contributions to health in Peru for more than 80 years. Roche has managed to hold a leading position in the market due to the high performance of its products and its collaborators. Research and development leading to constant innovation has allowed Roche to provide comprehensive solutions in different therapeutic lines and thus give more hope of life to many people. In the field of medical devices, Roche has a great expertise for in-vitro diagnostics and blood reagents.

For in-vitro diagnostic products and medical devices, Roche Q.F.S.A.⁶⁰ implements national regulations DS-010-97 (Regulation of Registration, Control and Sanitary Surveillance for Pharmaceutical and Sanitary Products) and DS-016-2011.

For medical devices, the national standard also recognizes the international reference of IMDRF (International Medical Device Regulation Forum). However, its application and adoption are irregular.

The authorization of in-vitro diagnostic reagents is not under risk classification. It means that all products have the same importance for the health authority (99% of the products are for professional use and 1% for patient use). In the case of medical devices, there is a risk classification and almost 100% of the products are for patient use.

Some of Roche technology:



cobas® pro integrated solutions enable to boost efficiency with fast analytical units, intelligent sample routing, and short assay incubation times. Physicians are empowered to take action faster, with best-in-class 9 minutes STAT and 18 minutes routine immunochemistry assays.

⁶⁰ Available on line: www.roche.com.pe/



cobas® 6800. As pioneers of polymerase chain reaction (PCR) technology, Roche continues to demonstrate its commitment to scientific and clinical excellence. Roche systems and assays are the trusted choice in clinical trials across the industry — from [plasma and blood screening](#) and viral load testing to more recent leadership with HPV primary screening and advances in oncology testing with the [cobas® EGFR Mutation Test v2](#). Roche holds its products to the highest performance standards to give you confidence in every result.



The Accu-Chek® Inform II system and the cobas® infinity POC IT solutions together support Point of Care coordinators, physicians, nurses, IT experts and infection control managers to better manage their complex working tasks.

Código de material: MC-PE-00616

Disclaimer: Roche images are for informational purposes only. Not all solutions are available in Peru and can be consulted through the company's official channels.



The Suiza Lab Group⁶¹ began operations 25 years ago offering comprehensive health care to its patients, based on the guarantee of a safe and timely diagnosis. Throughout the years they have implemented offices nationwide with the commitment to expand its coverage and reach all Peruvians, always hand in hand with first class professionals.

In addition to being a clinical laboratory, Suiza Lab is also a center for medical specialties and is the first certified international vaccination center in Peru. Its work goes beyond a medical consultation or routine examination as it is constantly innovating on the best technological tools to offer quality health care.

Its portfolio includes the following services:

- Clinical analysis laboratory with more than 3200 tests available.
- At the laboratory level, they have:
 - Clinical laboratory: routine tests, emergency tests, tumor markers and exotic tests.
 - Molecular biology laboratory
 - Pathological anatomy
 - Genetics
- Diagnostic imaging
- Special medical procedures and specialized tests
- Home health care
- Corporate medical check-ups

Regarding the current needs of the health sector in Peru, they explain that currently the clinical diagnostics sector is going through a stage of high growth driven by the boom of Covid tests that until 2021 was quite positive. Although this favors the decentralization of clinical diagnostics, it has also created an imbalance in the market, and the user now has many more options than they had in 2019, before the pandemic. The real work is to demonstrate the importance of a correct laboratory analysis, performed with high quality standards and accessible to the public, to ensure an improvement in the quality of life of patients. In short, the need is to have the certainty of a good laboratory result, efficient in time and at an affordable cost.

They consider that in hospitals and clinics, the greatest potential that Suiza Lab can target is to "complement" and support these services that, due to internal political or economic issues, cannot be covered, leaving their patients unattended and with high

⁶¹ Available online: www.suizalab.com

rates of dissatisfaction. This is where they can work together and offer alternatives close to hospitals and clinics with the quality that Suiza Lab already represents.

The opportunities that Suiza Lab finds for Swiss technology in Peru focus on the veracity and accuracy of the results that can be demonstrated through international certificates, the reputation and trust generated in the population, and the strategy of close patient care.



PANADEX Group⁶² is a leading company in the audiological market. It commercializes quality products and services with a culture based on principles of growth, efficiency and people in all its actions, oriented to provide an efficient and effective service to its customers. It distributes products manufactured in several countries around the world, including Switzerland, Denmark, the United States, Australia and Ireland.

PANADEX has worked with Swiss technology for more than 16 years. It has products from the Swiss Group SONOVA who owns the hearing aids' brands Phonak, Unitron, Hansaton and Advanced Bionics (cochlear implants). PANADEX has also products from Bien Air Medical Technologies (Le Noirmont, Switzerland) including otologic and rhinologic Solutions, micro-surgery equipment, micro-milling and micro-debrider.



PANADEX clients include companies, armed forces, EsSalud, Ministry of Health, Clinics, NGOs and, physicians.

With 28 years of experience and 22 selling points, PANADEX is the audiological leader in Peru with substantial market shares:

- Cochlear Implants (95%)
- Hearing aids (45%)
- Osteointegrated Implants (90%)

⁶² Available on line: <http://panadex.com/>

Regarding the registration and marketing authorization requirements, the Sanitary Registration issued by DIGEMID is indispensable, based on the manufacturer's Certificate of Free Sale.

Sales to public health institutions are made through open bids, and to private clinics through direct sales. Doctors purchase in general through direct sales. PANADEX distributes directly from manufacturers.



PANADEX usually participate in the World Congresses in Germany on audiology and the World Congresses of Otorhinolaryngology (ORL, ears, nose, throat). In Peru, Swiss contributions to medical technology are not well known.

PANADEX is interested to learn about Swiss technologies and to establish a B2B relationship with the representation of Swiss firms in Peru.



9. CONCLUSIONS / CALL-FOR-ACTION

1. Switzerland hosts a strong export-oriented Medtech industry. For the coming years, Peru will offer a rapidly growing market with only 5% of medical devices produced locally.
2. Swiss firms have a good presence in Peru for hearing aids and orthopedics.
3. In other areas – surgical instruments and techniques, radiology imaging, ophthalmology, in-vitro diagnostics, dental products, disinfectants and sterilization- the market shares of Swiss firms remain very low.
4. Looking at business opportunities, it is very encouraging to note that Swiss products are represented in high growth areas with in particular appliances for surgery, implants, ophthalmic instruments, reagents to determine bold groups and dental fittings. Market penetration could however be increased.
5. There is still much potential to be tackled for apparatus based on X-ray, ozone therapy and pace makers.
6. Swiss firms could continue to increase import penetration in lower growth market segments where they have gained market shares, namely instruments used in dental sciences and electro-diagnostic apparatus.
7. There is also a fairly large field of products with no Swiss presence. In 2019, Switzerland exported more than US\$120 million in these products to the world, mainly to Europe. Peru could also be envisaged in the future.
8. Regulatory requirements, logistics and distribution are key elements to enter successfully the Peruvian market. It is important to select well the product to be introduced in Peru, to be able to register it according to Peru's legal conditions, to have a strategic commercial partner to present the properties and advantages of the product to the clinics and hospitals, and who knows the different procedures of each institution.
9. A product, just by the fact that it is from Switzerland, is already an endorsement since Swiss products are accurate and precise.
10. Finally, if a Swiss company wants to export Medtech products to Peru it needs to establish its own drugstore to register the product, or hire a representative which must be a drugstore with a warehouse registered.

Call-for-action

The Swiss Chamber of Commerce in Peru, with 69 years of professional experience and with 150 partners in different business sectors, is an excellent ally in entering the Peruvian market.

With the elaboration of this report, the Chamber of Commerce has developed an exclusive expertise in the Medtech field for the benefit of Swiss companies.

Hospitals, medical doctors, dentists and patients need the best technology.

Swiss firms have a strong reputation and a lot to offer. They should rapidly increase their presence or establish it in Peru, a market for the future!

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10. ANNEXES

Annex 1. Main importers of Medtech products in Peru, 2019

Product (HS)	Name of the importers	Import value (CIF US\$ millions)	Market Share
3005	3M PERU S A	4.11	24%
	ALKHOFAR SOCIEDAD ANONIMA CERRADA	1.78	10%
	L & M MANUFACTURAS MEDICAS S.A.C.	1.17	7%
3006.10	JOHNSON & JOHNSON DEL PERU S.A	0.65	44%
	CARDIO PERFUSION E.I.R.LTDA	0.13	9%
	B.BRAUN MEDICAL PERU S.A.	0.12	8%
3006.20	DIAGNOSTICA PERUANA S.A.C.	0.75	61%
	DIAGNOSTICO UAL S.A.C.	0.16	13%
	SISTEMAS ANALITICOS SRL	0.13	11%
3006.30	MINISTERIO DE SALUD	4.89	43%
	CARDIO PERFUSION E.I.R.LTDA	2.97	26%
	BAYER S.A.	1.55	14%
3006.40	3M PERU S A	1.85	28%
	INVERSIONES RASMUSSEN SRL	0.53	8%
	E. B. PAREJA LECAROS S.A.	0.51	8%
3006.50	EMBAJADA DE LOS ESTADOS UNIDOS AMERICA	0.01	29%
	RUC: 0000022B	0.01	28%
	SOUTHERN PERU COPPER CORPORATION SUCURSA L DEL PERU	0.003	9%
3306.20	PROCTER & GAMBLE PERU S.R.L.	0.27	35%
	COLGATE-PALMOLIVE PERU S A	0.27	35%
	JOHNSON & JOHNSON DEL PERU S.A	0.18	23%
3307.90.10	VALEANT FARMACEUTICA PERU S.R.L.	0.24	37%
	OCULAB LATINOAMERICA SOCIEDAD ANONIMA CERRADA	0.16	24%
	ALCON PHARMACEUTICAL DEL PERU SA	0.13	21%
3401.11	COLGATE-PALMOLIVE PERU S A	11.4	31%
	UNILEVER ANDINA PERU S.A.	8.12	22%
	PUIG PERU S.A.	5.50	15%
3808.94	QUIMTIA S.A.	0.89	7%
	INTERNATIONAL COMMERCE COMPANY S.A.C.	0.76	6%
	MERCANTIL S A	0.75	6%
3822	PRODUCTOS ROCHE Q F S A	8.64	16%
	DIAGNOSTICA PERUANA S.A.C.	3.82	7%
	REPRESENTACIONES MEDICAS DEL PERU S.R.L.	2.95	5%
4014	MINISTERIO DE SALUD	2.12	29%
	APOYO A PROGRAMAS DE POBLACION	1.70	24%
	MEDIFARMA S A	1.19	16%
4015.11	LABORATORIOS AMERICANOS S.A.	2.34	16%
	UTILITARIOS MEDICOS S.A.C.	2.30	15%
	ALKHOFAR SOCIEDAD ANONIMA CERRADA	2.23	15%

	OPTICAS SHUAN EIRL	0.008	32%
701510	VENTURA CORPORATION OPTICAL S.A.C. IMPORTACIONES AGURTO SOCIEDAD ANONIMA CERRADA - IMPAGURT S.A.C.	0.006 0.004	24% 18%
7018	UNIQUE S.A. 3M PERU S A QUIMICA ANDERS SAC	1.27 0.59 0.59	26% 12% 12%
8419.20	MEDSTEP PERU S.A.C. AMERICAN HOSP SCIEF EQUIP CO DEL PERU SA VITALTEC S.A.C.	0.38 0.35 0.21	13% 11% 7%
9001	TOPSA RETAIL S.A.C. OPTICAS GMO PERU S.A.C GLOBAL MEGA SOCIEDAD ANONIMA CERRADA	2.89 2.18 1.29	16% 12% 7%
900130	VALEANT FARMACEUTICA PERU S.R.L. TOPSA RETAIL S.A.C. ALCON PHARMACEUTICAL DEL PERU SA	0.58 0.57 0.55	26% 26% 25%
9001.40	TOPSA RETAIL S.A.C. INVERSIONES OPTICAS SOCIEDAD ANONIMA CERRADA AGURTO & MORVELI E HIJOS S.A.C.	0.56 0.31 0.23	28% 16% 12%
9001.50	OPTICAS GMO PERU S.A.C TOPSA RETAIL S.A.C. GLOBAL MEGA SOCIEDAD ANONIMA CERRADA	2.18 1.74 1.29	19% 15% 11%
9003	OPTICAS GMO PERU S.A.C TOPSA RETAIL S.A.C. MB CORP INTERNATIONAL SOCIEDAD ANONIMA CERRADA	8.28 2.10 1.49	40% 10% 7%
9004	OPTICAS GMO PERU S.A.C TOPSA RETAIL S.A.C. 3M PERU S A	5.05 1.91 1.54	19% 7% 6%
9018	NIPRO MEDICAL CORPORATION SUCURSAL DEL PERU B.BRAUN MEDICAL PERU S.A. COVIDIEN PERU S.A.	13.04 8.55 5.72	6% 4% 2%
9019	COVIDIEN PERU S.A. Q.P.R. SAC JP REHAB S.R.L.	0.92 0.79 0.59	7% 6% 5%
9020	3M PERU S A MSA DEL PERU S.A.C. ANDES SEGURIDAD S.A.C.	15.27 10.44 1.60	50% 34% 5%
9021	JOHNSON & JOHNSON DEL PERU S.A COVIDIEN PERU S.A. ENDO MEDICA INVERSIONES S.A.C.	4.76 4.12 2.87	9% 8% 6%
9022	SIEMENS HEALTHCARE S.A.C GE HEALTHCARE DEL PERU S.A.C. ROCA S.A.C.	6.40 5.98 4.04	14% 13% 9%
9402	REPRESENTACIONES MEDICAS M & M EIRL A JAIME ROJAS REPRESENTACIONES GRLES SA MEDICAL DIGITAL EIRL	0.92 0.53 0.36	9% 5% 4%

Source: ADEX Data Trade platform
Elaboration: Swiss Chamber of Commerce in Peru (CCSP)

Annex 2. Swiss exports of Medtech products to Peru by category, 2017-2019

Category	Product at 6-digit HS level	2017-2019* US\$
Orthopedic	Orthopedic or fracture appliances (HS 9021.10)	8,193,970
Surgical	Medical, surgical or dental instruments and appliances (HS 9018.90)	4,044,735
Ophthalmology	Ophthalmic instruments and appliances (HS 9018.50)	2,617,998
Dental medicine	Instruments and appliances used in dental sciences (HS 9018.49)	1,918,859
Surgical	Catheters, cannulae and the like (HS 9018.39)	1,068,591
Surgical	Ozone, oxygen or aerosol therapy, artificial respiration or other therapeutic respiration apparatus (HS 9019.20)	1,028,395
Dental medicine	Dental cements, fillings and bone reconstruction cements (HS 3006.40)	946,211
In-vitro diagnosis	Reagents for determining blood groups or blood factors (HS 3006.20).	829,030
Hearing aids	Hearing aids (HS 9021.40)	665,214
Surgical	Mechano-therapy appliances; massage apparatus and psychological aptitude-testing apparatus (HS 9019.10)	597,747
Radiology imaging	X-ray generators other than X-ray tubes, high tension generators, control panels and desks, screens, exam Electro-diagnostic apparatus (HS 9018.19)	582,862
Dental medicine	Dental fittings (HS 9021.29)	437,350
Orthopedic	Artificial parts of the body (HS 9021.31)	346,072
Surgical	Syringes, with or without needles (HS 9018.31)	329,036
Radiology imaging	Apparatus based on the use of X-rays (HS 9022.19)	300,943
Surgical	Tubular metal needles and needles for sutures (HS 9018.32)	102,205
Radiology imaging	Ination or treatment tables, chairs and the like (HS 9022.90)	90,665
Radiology imaging	X-ray tubes (HS 9022.30)	89,223
Radiology imaging	Electro-cardiographs (HS 9018.11)	78,142
Disinfectants	Disinfectants and similar products (HS 3808.94)	71,776
Surgical	Adhesive dressings and other articles having an adhesive layer (HS 3005.10)	48,199
Surgical	Wadding, gauze, bandages and similar articles (HS 3005.90)	126
Ophthalmology	Spectacles, goggles and the like, corrective, protective or other (HS 9004.90)	92

Note: * for each 6-digit position, the figure is the highest during the 2017-19 period.

Source: Swiss Customs Administration, Bern, Switzerland, Swiss Impex.
Elaboration by CCSP.

Annex 3. Questionnaire sent to Medtech importers

A questionnaire was sent as Google Forms to twenty importing companies customizing questions 2 and 3.

PERU MEDICAL DEVICES PROJECT QUESTIONNAIRE

Switzerland has approximately 1,400 companies in the Medtech sector, employing 63,000 people and generating yearly sales of CHF 17.9 billion.

The Medtech industry exported goods worth CHF 12.0 billion in 2019, which corresponds to 5.0% of all Swiss exports. Switzerland exports three times more medical devices per capita than Germany, the largest Medtech producer in Europe. The major export markets are the European Union (46%), the United States (27.5%) and the rest of the world (26.5%).

Swiss exports of Medtech products account for about 70% of total production.

Swiss companies offer world-class technologies and are in particular active in the following areas:

- Orthopedics
- Ophthalmology
- In vitro diagnostics
- Radiology imaging
- Surgical instruments and techniques
- Disinfectants and sterilization
- Dental
- Ears

Peru purchases medical devices in all these areas.

The following questionnaire inquires on the needs of specific Peruvian purchasers and on their possible interest to become familiar with the Swiss products.

Phone:

Web page:

Contact person:

Contact e-mail:

1. Who are your main customers as an importer?

- | | |
|--------------------------|---------------------------------|
| <input type="checkbox"/> | Hospital |
| <input type="checkbox"/> | Medical Post |
| <input type="checkbox"/> | Practicing physician or dentist |
| <input type="checkbox"/> | Pharmacy |
| <input type="checkbox"/> | Other |

2. Do you purchase medical products from the above categories for your customers?

- | | |
|--------------------------|-----|
| <input type="checkbox"/> | Yes |
| <input type="checkbox"/> | No |

3. Do you purchase any of the following products for your customers?

3.1. Orthopedics

- | | |
|--------------------------|--|
| <input type="checkbox"/> | Bone regeneration |
| <input type="checkbox"/> | Cartilage regeneration |
| <input type="checkbox"/> | Total hip replacement |
| <input type="checkbox"/> | Hip replacement |
| <input type="checkbox"/> | Shoulder implant |
| <input type="checkbox"/> | Spine fusion surgery: minimally invasive |
| <input type="checkbox"/> | Hand |
| <input type="checkbox"/> | Wrist |
| <input type="checkbox"/> | Forearm |

- Elbow
- Shoulder
- Foot
- Mandible

3.2. Ophtamology

- Photocoagulator for retinal needs
- Multispot laser
- Cataract: fully integrated laser
- Glaucoma: laser
- Surgical platforms for eye surgery
- Instruments: laser probe, diathermy
- Laser for refractive, cararact and therapeutic surgery
- Refractive, cararact and therapeutic surgery: planning, evaluation
- DCT Technology: detect elevated IOP at a very early stage (glaucoma)

3.3. In vitro diagnostics

- Hemostasis diagnostics solutions and products portfolio: very broad and includes substrates, inhibitors, biochemicals, snake venom enzymes and kits and reagents
- Customized solutions
- Analytical units with pro-integrated solutions: intelligent sample routing, and short assay incubation times. Physicians are empowered to take action faster
- Anatomical pathology labs to diagnose cancer: pathology lab instruments, tissue-based clinical assays and software solutions; products offer prompt, precise tissue-based results so pathologists, physicians and patients can make confident treatment decisions
- Donor screening: complete donor screening solution to blood centres and plasma fractionators; commitment to keeping the blood and plasma supply safe
- Tackling infectious diseases through a suite of molecular diagnostic systems and assays that aid in the detection of virulent pathogens and drug-resistant bacteria
- Lab configuration for: cardiac, oncology, pregnancy care, thyroid, infectious diseases and companion diagnostic tests
- Molecular diagnostics: in vitro diagnostics, automation and molecular diagnostic testing
- 3D cell culture technologies: platform enabling high-quality, scalable and safe cell growth, cell cultivation and a correct cell programming with ability to translate into diagnostic and clinical use – as well as safe use of stem cells

3.4. Radiology imaging

- High quality products in X-ray technology: digital imaging; retrofit solutions
- X-ray components: carrier units, generators
- Film development
- Disinfection stand
- Supplies solutions for the optimal positioning, fixation and placement of patients: multipad, headfix, babyfix cocoon, crania
- High-resolution, non-destructive 3D imaging of specimens *in vitro*
- Osteoporosis: monitoring bone microstructure, in addition to bone mass in patients; high-performance, high-resolution system that combines high-speed scanning, low X-ray dose and true 3D analysis to provide a unique solution for clinical monitoring and treatment of osteoporosis patients
- Software offering a comprehensive solution for scanning, 3D analysis, visualization, data management and data import/export
- Scan service: high-resolution scanning and 3D analysis

3.5. Surgical instruments and techniques

- Navigation system for minimally invasive treatment of cancer tumors in the liver, lung, kidney, pancreas and bones which provides at the end of the procedure clarity on the success
- Robotic surgical system for high precision minimally invasive cochlear implantation
- Precise robotic surgery system with fully articulated, single-use 8 mm instruments for suturing and dissection: needle drivers, Johann graspers, monopolar scissors, monopolar hooks and bipolar Maryland forceps
- Navigated hip replacement: the surgery is planned with the help of X-ray images. The navigation system then helps him during the operation to insert the prosthesis exactly as

- planned and with great accuracy. The more precisely the prosthesis is inserted, the longer its life and the lower the risk for complications
- Instruments for surgery, orthopedic and traumatology
- Instrumentarium for hip preservation surgery

3.6. Disinfectants and sterilisation

- Hand disinfectant: for hygienic and surgical hand disinfection
- Disinfectant for surfaces and instruments: formaldehyde-free
- Ready-to-use alcohol-based rapid disinfectant: for wipe or spray disinfection of small areas and medical equipment
- Cleaning concentrate: Product data sheets
- Hand and skin disinfectant
- Disinfection of instruments
- Detergents
- Surfaces and medical equipment

3.7. Dental

- Ridge preservation to conserve more than 90% of the volume following tooth extraction
- Immediate implant placement: filling the gap between the implant and the buccal bone plate reduces bone resorption and enhances aesthetic outcome
- Guided bone regeneration: surgical procedure that uses grafting materials and barrier membranes to stimulate and direct the growth of new bone at defect sites
- Minor bone augmentation; sinus elevation
- Denture Base Material
- Impression Materials
- Laboratory Silicone
- Non Allergic Products
- Crown and Bridge Composite
- Orthodontic Acrylic
- Pattern Resin
- Tray Materials
- Isolation & Lacquer
- Separating Agent
- Alledent Products
- Implantology
- Prosthodontic
- Advanced biomaterials
- Digital solutions
- Orthodontic

3.8 Ears

- Hearing aid
- Hearing aid with pediatric solutions with more communication power
- Multifunctional hearing aid
- 100% invisible hearing aid
- Hearing aids to boost hearing performance in loud noise and over distance
- Cochlear implant system: includes several pieces of technology that work together to bypass the cochlea—restoring hearing by sending sound directly to the hearing nerve

Would you or the customers like more information about the above products?

- Yes
- No

4. How important is training to the use of the medical products in points 2 and 3? How is it provided for foreign products?

5. For which categories of products in items 2 and 3 is an authorization (quality, safety, efficacy) and a marketing authorization (method of sale; information for the practitioner and for the patient) required?

5.1. Do the Peruvian authorities recognize the authorizations of the U.S. Food and Drug Administration (FDA) or the European Medicines Agency (EMA) for some of the products in items 2 and 3?

6. Are the products of items 2 and 3 subject to national or international standards?
7. Which of the medical products in items 2 and 3 are also sold locally?
8. What is the country of origin of the main foreign-made medical products of item 2 that you sell and/or use?

We thank you for your valuable collaboration with this important study that we will send you once it is completed.