Optimal
A Keralty company

Optimal's Playbook:
Essential requirements for **U.S.** vendors to import, market, and sell in **Colombia** with Optimal

Optimal process map

One off

Sales agreement between **Manufacturer USA** & **Optimal**

Sales & importer agreement between **Optimal** & **Distributor CO**

D. CO holds required CCAA certifications

M. USA authorizes IOR role in Health Registration to **D. CO**

FF / CB USA conducts export clearance on behalf of **Optimal**

Optimal makes the payment to **M. USA**

shipment and pickup order between **M. USA** & **Freight Forwarder / Customs Broker USA. Optimal** is the exporter.

Purchase and sales orders take place

FF / CB USA delivers at CO seaport to **Customs Broker CO**

CB CO conducts import clearance on behalf of **D. CO**

CB CO delivers to **D. CO**

D. CO distributes to **Colsanitas CO**

D. CO makes payment to **Optimal**

Map legend

M. USA = Manufacturer USA / D. CO = Distributor CO
FF / CB USA = Freight Forwarder / Customs Broker USA / CB CO = Customs Broker CO
C. CO = Colsanitas CO

This is what U.S. vendors need to import, market, and sell in Colombia with Optimal

• NDA signing:
The first step is to sign an NDA (Non-Disclosure Agreement) with Optimal in which both parties agree that all the information exchanged with each other will not be revealed nor shared with third parties.

• XRef:
Depending on the type of product your company offers, a product cross-reference (xRef) should be conducted by your team to establish equivalency between your products and ours. This ensures that the items in your portfolio are suitable substitutes or, at the very least, viable alternatives to the products we currently procure.

We will provide you with a file containing the following information:

- Material code
- Category
- Product description
- Vendor/Manufacturer
- UoM/Unit of Sale
- Quantity Acquired (over a period of time)

• Export licensing: Verify if your product calls for any export licensing. In order to do this, you should:

- Learn the Schedule B (Harmonized Tariff Schedule) code for your product. Should you have any doubts over your product's Schedule B HTS code, please refer to the following websites:

Official United States Government site:
https://hts.usitc.gov/search

United States Census Bureau:
https://uscensus.prod.3ceonline.com/#!#current-question-pos

- Confirm if your product falls within the scope of the EAR (Export Administration Regulations) and is given the classification of EAR99, which is the category that lists products that can generally be exported without license.

International Trade Administration:
https://www.trade.gov/eccn-and-export-administration-regulation-ear99

- If you do not succeed in finding your product on the above listing, please confirm if your product is on Commerce Control List (CCL) with an Export Control Classification Number (ECCN). Products on this list require export licensing to leave the USA.

Bureau of Industry and Security:
https://www.bis.doc.gov/index.php/regulations/commerce-control-list-ccl

International Trade Administration:
https://www.trade.gov/how-do-i-determine-my-export-control-classification-number-eccn

Official United States Government site:
https://www.govinfo.gov/content/pkg/CFR-2012-title15-vol2/pdf/CFR-2012-title15-vol2-part774-appNo-.pdf

• **Samples:** Once you are certain that your products can leave the USA without restriction, a sample requirement from our customer in Colombia should be met. Non-commercial-value medical devices and biomedical equipment samples have a specific treatment by Colombian Customs, for this reason, this topic will be explored more in detail later on in this manual.

• **Price offer:** The next step is to make a price offer in which the payment and delivery terms are open to negotiation with Optimal.

• **Customs Brokerage and Freight Forwarding:** If you do not have any experience in international trade transactions, in this case, exporting, it will be very likely that you need a Customs Broker or a Freight Forwarder so as to carry out all the export clearance processes. Depending on the delivery terms negotiated with Optimal in the USA, you will have to contract out or not the services of the above providers. In the event that you need to, we suggest the below companies:

- **Customs Brokerage:** Posey International
  https://posey-intl.com/

- **Freight Forwarding:** Diversified Transportation Services
  https://www.dtsone.com/

• **Health Registration in CO:** Depending on the nature and end use of your product, you will need a sanitary registration in CO (Colombia), issued by INVIMA-Instituto Nacional de Vigilancia de Medicamentos y Alimentos- (Colombian Food and Drug Administration counterpart). This registration can take between 2 to 9 months, but this timeframe certainly depends on the complexity of your product. ***Most medical devices and biomedical equipment require this permit.***

- In order to get a sanitary registration, you will need to outsource the application process to a RA (Regulatory Affairs) consulting firm that acts on behalf of you before INVIMA via power of attorney. We work at the moment with a known quantity family owned company with more than 10 years in business Colombia, specialized in DME and pharmaceutical regulatory affairs. Please feel free to reach out them if need be:

  Consulting Firm: RA Colombia SAS
  https://www.asuntos-regulatorios.com/asesoria-regulatoria-farmacovigilancia/

- Throughout the application, INVIMA will ask you as a manufacturer, for technical and quality information about your product and also to design a mandatory regulatory labeling, both of which will be discussed in greater detail later on in this manual. This Colombian sanitary registration will allow you:

  ☑ To import
  ☑ To market
  ☑ To prepare/pack
  ☑ To sell

• **Customs clearance in CO:** As it relates to import customs clearance in CO, you will also be in need of an importer of record that will be listed on your sanitary registration and will be the passive subject to import taxes (VAT and tariffs) if applicable.

Optimal offers a sister company fully operative in Colombia that has successfully served this purpose in the past with many other vendors. Here are their details:

Importer of record: Praxis Clinic Colombia LTDA
https://caihcron.com/praxisclinicolombia/

- In most cases, a 3PL (Third-Party Logistics) that supports the importer of record's warehouse storage, picking and packing, labeling and delivery operations in Colombia will be necessary as well. This company will have to comply with either a CCPHD (Certificado de Capacidad de Producción de Productos de Higiene Doméstica y Absorbentes) or a CCAA (Certificado de Capacidad de Almacenamiento y/o Acondicionamiento de Dispositivos Médicos) certifications issued by INVIMA, depending on the nature and end use of your product. Praxis Clinic Colombia has a partnership with a well-known 3PL company located in Bogota's FTZ (Free Trade Zone) that is compliant with all the above. Here are their details:

Third-Party Logistics Company: Grupo A&C Zona Franca S.A.S.
https://www.grupoayczonafranca.com/

- A Colombian Customs Broker will be needed in order to carry out import customs clearance on your behalf before DIAN (Colombian Internal Revenue Service and Customs Border Protection) and to apply for the required Import Licensing that is a must for medical devices, biomedical equipment, hygiene products, medicines, cosmetics, food and beverages that call for a sanitary registration in Colombia. Praxis Clinic Colombia has a long-lasting commercial relationship with a known quantity Customs Broker that will be in charge of import formalities. Here are their details:

Customs Brokerage in Colombia: Asociación Aduanera Internacional SAS, Agencia de Aduanas https:// AAInternacional.com/

- **Training and after-sales technical/customer service**

When it comes to introducing a new product or technology to a Hospital or Medical center, the educational component is fundamental for us. In consequence, this playbook will address this matter in depth later on in this manual. As for the after-sales technical and customer service, it is essential that you bear in mind that in CO, by law, a preventive maintenance a year is mandatory as it relates to biomedical equipment and that, by company policy, the after-sales service must be provided either on-line with virtual offices or call centers, or in presence with a technician.

- **Distribution Agreement placement (Legal Affairs):**

This section in particular is one of the most important ones. The contractual agreement between your company and Optimal has to be under negotiation and happening in parallel with all the other above activities and processes, since this document must cover all the terms agreed upon during the negotiation. Arriving at this agreement with all the subjects reviewed, discussed and included might take a couple of months, this is why we urge that you carry out this task simultaneously.

Samples

- Once we get to the Samples stage, you will receive a sample request form from us with all the information on the samples we require, delivery and ship-to details. This request should be approved, signed and sent back to us with the information about samples' shipment. You will find an example of this form on the next page.

- Any medical device, medicine or cosmetic intended to be imported into CO must comply with several sanitary requirements and also with an import licensing before clearing customs. This kind of products cannot be shipped out by courier for the above reasons, however when it comes to samples and the following conditions are met, there exists a fair chance that they can go through customs as a courier parcel without major issues:

- The invoice value cannot exceed **USD $2,000.**
- The parcel cannot weigh more than 50Kg.
- Parcel's dimensions cannot exceed 1.5 m on each side.
- There must be no more than 5 units of product per reference or model inside the parcel.

- If for whatever reason, the quantity of products to be shipped exceeds 5 units, the parcel should be split up into as many smaller shipments as possible, each of them with different CNEE (Consignees) and ship-to addresses. Here you are our addresses:

Cnee 1:
Keralty S.A.S / NIT: 800125872-5
Calle 100 # 11B - 67 / Bogotá, Colombia
Attn: Johan Castro / **Tel:** 3187757799

Cnee 2:
Praxis Clinic Colombia Ltda / NIT: 900168614-9
Ak 45 # 103 - 19 Piso 1 / Bogotá, Colombia
Attn: Johan Castro / **Tel:** 3187757799

Cnee 3:
Oftalmosanitas S.A.S / NIT: 830103525-9
Calle 134 # 7B - 83 Oficina 315
Bogotá, Colombia
Attn: Johan Castro / **Tel:** 3187757799

- All samples' shipments must be invoiced and have unit and total values per reference, this is for customs valuation purposes. Please bear in mind that even though the samples are FOC (Free of Charge), they still levy import taxes that must be paid at destination based on the invoice value. In your invoice's remark section there must be the following statement that will help customs' officers know that these products are samples:

FOC products. Values only for Customs valuation purposes.

Sanitary (Health) Registration in CO

When applying for the sanitary registration of your products in Colombia, you will be requested by the INVIMA to provide them with the following documents. Depending on how complex (risk analysis) your product is, you will probably be asked for some other information, but in general the below will be enough to get your application rolling:

Document	Explanation
Application form properly filled out, in both physical and electronic formats (Excel file)	It must be approved by the technical director and signed by the legal representative or attorney. If the form contains attachments, they must be included in the same format.
Power of Attorney (if applicable)	**POWER OF ATTORNEY** to process the health registration (if applicable). When the request is submitted by an attorney, one of the two types of powers of attorney listed below must be provided: **Special Power of Attorney. Must contain:** • The name of the principal (Legal representative or the person authorized by delegation) • The name of the licensed attorney • The procedures for which the attorney is authorized **General Power of Attorney:** • The public deed or Certificate of existence or legal representation where the name of the attorney is evidenced. **Note:** Either of the two types of power of attorney listed above may be provided with the request. **For powers of attorney granted abroad:** Please submit a properly constituted power of attorney, in accordance with Article 19, subsection b) of Decree 4725 of 2005 and Article 74 of the General Procedural Code.
Original payment receipt	It must correspond to the procedure under the appropriate legal fee.

Document	Explanation
Certificate of Free Sale -FSC- (Imported Products)	The document must meet the following requirements: **1.** It must be issued by the health authority of the country of origin or a reference country (Canada, Japan, Australia, European Union, or the United States). **2.** It must indicate the name of the manufacturer(s), the name of the medical device or Biomedical Equipment along with their references that are to be covered. **3.** If the Free Sale Certificate does not state a validity period, it will be valid for one (1) year from the date of issuance; otherwise, the validity specified in the document will apply. **4.** It must be consularized and legalized or, if applicable, apostilled if the country is part of the Hague Convention. **5.** It must be accompanied by an official translation.
Manufacturer Authorization (Imported Products)	This document must meet the following requirements: **1.** It must indicate the name of the importer and their address. **2.** It must specify the roles and activities that the new importer will carry out in the health registration in accordance with current health regulations. **3.** It must be signed and authorized by the holder of the health registration and/or marketing authorization.
Certificate of Storage Capacity (CCAA) or Good Manufacturing Practices (GPM) for medical devices and/or certificate of technical sanitary conditions.	Indicate the date and the filing number with which the Certificate of Storage Capacity (CCAA) or Good Manufacturing Practices (GMP) for Medical Devices and/or Certificate of Technical Sanitary Conditions was issued (DD/MM/YYYY) //_____; Filing number _____ As per the Anti-Red Tape Decree 019 of 2012, it will be reviewed internally by the Institute.

Document	Explanation
	A) In the case where the Medical Device is imported for personal use, a certification must be attached stating that the product will be for personal use and will not be sold. "Personal Use is understood as when the Medical Device does not leave the institution's possession." This applies to medical devices that are not for single use (e.g., stethoscopes, organ equipment, blood pressure monitors, among others). **B)** For imported Medical Devices, please note that this concept must be approved within the Certificate of Storage Capacity (CCAA). If you are requesting a health registration for a new product that is not covered in the CCAA Certificate, you must provide a copy of the notification filing to the Technical Group of the Medical Devices Directorate indicating the new product line to be imported.
Description of the Medical Device	**The description must include:** indications, contraindications, warnings, main components, accessories, and relationship with patients; all in Spanish. Please remember that the commercial presentation corresponds to the definition of the number of units/content per package/container as the manufacturer and/or importer markets the product and as authorized in the health registration.
Technical Studies and Analytical Checks	**A)** Summary of the verification and validation documents of the design (test report during the manufacturing process). **B)** Certificate of analysis of the finished product containing the specifications, indicating the values or acceptance ranges. It is required to establish that the design complies with the current specific technical standards and regulations.
Declaration of Conformity (Issued by the Manufacturer)	When the Free Sale Certificate (FSC) only declares product families by reference, the applicant must submit the manufacturer's Declaration of Conformity, specifying that under the family names described in the FSC, the subfamilies of the references are included. These must match those indicated by the applicant in the application form.

Document	Explanation
Sterilization Method	Indicate the method(s) utilized along with their procedures, the reference standard upon which they are based, and the studies conducted, results, and conclusions. If the sterilization method of the product is performed using ethylene oxide, studies demonstrating the post-sterilization residue must be attached.
Disposal or final disposition method	Description of the disposal or final disposition method of the medical device issued by the manufacturer, or alternatively, the description provided by the authorized importer along with the insert specifying the disposal or final disposition method of the medical device will be accepted.
Lifetime (if applicable)	For sterile Medical Devices or non-sterile products that declare a life cycle, this requirement is considered fulfilled by attaching stability studies that validate the attributed lifetime, including a summary of the applied method and procedure, verification, validation, and final result. For products that do not declare a lifetime, no manufacturer declaration will be required. **A)** Manufacturer's labels must be submitted, showing at a minimum: product name or reference, manufacturer's name and address, and internationally recognized safety symbols. **B)** Importer's sticker (label) indicating the product name, model and/or reference, importer's name and address, and Health Registration number (I, IIA, IIB, and III).
Scientific information supporting the safety of the medical device (Risk classes IIa, IIb, and III)	Biological evaluation tests of the product must be attached (studies of cytotoxicity, systemic toxicity, pyrogenicity, sensitization, irritation or intracutaneous reactivity, genotoxicity, allergenicity, hemocompatibility, and carcinogenicity), according to the device. These apply to devices in direct contact with the patient, and a summary of the studies and tests conducted must be provided.

Document	Explanation
	When the technologies are sufficiently demonstrated, this requirement can be fulfilled by providing scientific evidence indexed or published in internationally recognized journals, relating to the biological evaluation of the specific material for the medical device subject to the health registration request. For active medical devices (those dependent on an energy source for operation), scientific information supporting the safety of the Medical Device (risk classes IIa, IIb, and III) must be provided. This includes the development of electrical tests and electromagnetic compatibility (e.g., IEC standards), in accordance with current international regulations.
Risk analysis issued by the manufacturer for medical devices (Risk classes IIa, IIb, and III)	The analysis must mention the risks identified during the design and manufacturing stages, their causes, severity, occurrence, detectability, and proposed solutions for mitigating each risk.
List of standards used	Indicate on the list the international reference standards that have been applied, either fully or partially, if applicable.
Commercial history of the medical device (Imported Products)	List the countries where the medical device is sold and indicate any Health Alerts related to the medical device that is the subject of the Health Registration request. (Issued by the product's manufacturer).
Clinical Studies (Risk classes IIb, and III)	They must be conducted on patients to demonstrate safety and effectiveness. Published clinical studies of similar or equivalent technologies to those presented in the health registration application can be submitted.
Implantable card	An artwork must be attached, displaying the following information: the name and model of the medical device, batch number or serial number, manufacturer's address, the name of the institution where the implant was performed, the date of the procedure, and patient identification. Refer to the definition in Article 2 of Decree 4725 for "implantable medical device" (applies to products that remain in the body for more than thirty (30) days) for Risk Classes IIb and III.

Risk categories

Class I

These are low-risk devices, subject to general controls. They are not intended to support or sustain life, nor for use in preventing significant deterioration of human health, and they do not pose an unreasonable potential risk of illness or injury.
Timeframe I: Automatic Health Registration from 45 to 60 calendar days (subject to post-approval control).

Class IIa

These devices carry a moderate risk and require specific manufacturing controls to ensure their safety and effectiveness.
Timeframe IIa: Automatic Health Registration from 3 to 5 months (subject to post-approval control).

Class IIb

These are high-risk devices, subject to special controls in both design and manufacturing to demonstrate their safety and effectiveness.

Class III

These are very high-risk devices, subject to special controls. They are designed to support or sustain life, prevent significant deterioration of human health, or they may pose a potential risk of illness or injury.

Timeframe IIb and III: Regular Health Registration / Marketing authorization from 8 to 10 months (subject to pre-approval control).

Labeling

Every medical device or biomedical equipment that wants to be marketed and sold in Colombia must comply with a specific labeling/marking technical standard requested by INVIMA. This labeling/marking requirement can be met in the USA or in Colombia and depending on the product complexity and INVIMA's risk assessment/categorization, it should include different and specific information on it.

The information required by INVIMA can be printed directly on products' primary packaging or on a label or sticker, this label must be fully in Spanish and you should make sure not to cover or hide any original or factory product information. The below example shows the most common information requested by the INVIMA to be on the product or on a label/sticker, but please bear in mind that the required information can change based on the nature of your product.

Importer's stickers

When the medical device or biomedical equipment includes an insert, it must contain sufficient information in Spanish to ensure the proper execution of the procedure and safe use. The insert must be supplied along with the medical device or biomedical equipment, without the need for it to be inside the packaging.

BERHOL S.A.

Glucómetro

1. Entrada de sangre a la tira
2. Tira de pruebas
3. Contacto tira salida
4. Pantalla LCD
5. Botón sacar tira

Modo de uso:

Aprieta el dedo hasta que se forme una gota de sangre

Coloca la gota de sangre en la tira reactiva

Espera hasta que el glucómetro muestre los resultados

Observa y anota los resultados

Precaución:

No comparta con nadie, incluso familiares, el equipo de monitoreo del azúcar en la sangre, como las lancetas.

Guarde las tiras de prueba en el recipiente suministrado

Registo sanitario:

INVIMA (AÑO) -
DM (CONSECUTIVO)

Información del fabricante extranjero:

BERHOL S.A.
Tel: (+601) 5423901
Carrera 65A #74-41
BERHOLSA@gmail.com
Bogotá, D.C.
Colombia

Please be advised that if you use any symbology on products or/and in the insert that comes along with them, you should use the international symbology system related to the specific information you want to communicate. Here you have a few examples of the most used ones in the industry.

Fabricante

Fecha de fabricación

Fecha de caducidad

Códifo de lote

Número de referencia y/o modelo

Dospositivo médico

Número de serie

No utilizar si el paquete está dañado

Consulte las instrucciones de uso

RxOnly

Solo para uso con prescripción médica

QTY

Cantidad

Non-pyrogenic

Pieza aplicada tipo BF

Estéril

Sistema de barrera estéril (irradiación)

Sistema de barrera estéril (óxido de etileno)

Esterilizado con radiación gamma

Esterilizado mediante óxido de etileno

Esterilizado usando técnicas asépticas

Esterilizado con calor seco o húmedo

Training

Training and education when implementing and deploying medical devices and biomedical equipment is vital if we want to develop end-user attachment to the new products. The first step is gathering all the **medical/clinical literature, bibliography and technical information** related to your product in Spanish. This phase is critical since it is the starting point of any educational relationship with the actual users of your product. All this information allows nurses, clinicians, practitioners, biomedical engineers and pharmaceutical chemists to update their knowledge, raise questions and in general to give you feedback when the time for training comes.

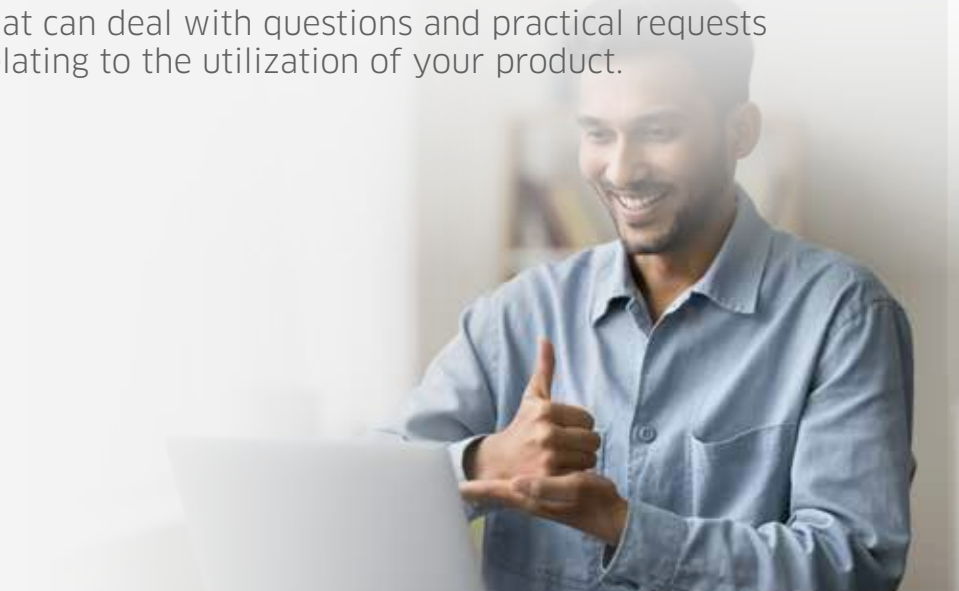
The second step addresses the training per-se. This activity takes place in three different stages, as follows:

A major project launch with all the clinician, nursing, medical, engineering and pharmaceutical leaders that will be in contact with your product. This launch can be on-site (in person) or on-line, depending on the specific training requirements.

A trial run carried out in the company of the healthcare personnel in charge of your product handling and use at the hospitals and clinic centers chosen by the corporation based on your product´s utilization rate. This pilot test must be done in Spanish and all the information, deliverables and handouts provided have to be in Spanish too.

- **Final virtual accompanying and assistance** for specific professionals and health centers that for different reasons such as location and availability could not be trained at the first two educational stages.

The last step has to do with the after-roll-out training service. There should be a call center or a web office that can deal with questions and practical requests relating to the utilization of your product.



	Checklist	☑
USA	NDA (Non-Disclosure Agreement)	
	Cross-Reference (Xref)	
	Schedule B (HTS) Code	
	Export Control Classification Number (ECCN/EAR99)	
	Samples	
	Price offer	
	Freight Forwarder/Customs Broker in the USA	
Colombia	Consulting firm	
	Importer of Record	
	3PL (Third Party Logistics)	
	CCAA Certificate (INVIMA)	
	Labeling/marking technical standard	
	Sanitary Registration (INVIMA)	
	Customs Broker	
	Import licensing (Customs Broker)	
	Training	
	DA (Distribution Agreement)	


Optimal
A Keralty company