A **secure** and **controlled** regulatory and business environment for your operations in Brazil

ANVISA BRAZIL

→ **Registering** and **managing** your products in Brazil and / or in Latin America

- Medical devices
- Cosmetics
- Pharmaceuticals / Drugs
- Sanitary products
- Food & Supplements

MANDALA INTERNATIONAL

Fundamentals
for doing business in Brazil

To market health and beauty products in Brazil, you must first register with the appropriate local agency: **ANVISA, Brazil's National Health Surveillance Agency.**

This registration must be obtained before any commercial application for the following types of products.

- **Medical Devices**
- **Cosmetics**
- **Pharmaceuticals and drugs**
- **Sanitary Products**
- **Food & Supplements**

This administratively complex process involves a high level of risk.

Our services are intended to reduce this risk (commercial, legal, and technical) by taking these time-consuming steps for you.

Good to Know

Beyond navigating complex administrative issues, our work deals with a number of practices unique to Portuguese business culture.

- **Registration must be requested through a local and reputable Brazilian company that will own these records EXCLUSIVELY for five years,**
- The company must be in good standing and fully authorized by ANVISA including its infrastructure,
- This procedure is different and more complex than FDA,
- The application process takes 6 to 12 months at least before your registration goes into effect,
- The registration is always held by the company that filed the application.

Only three options **to access the Brazilian Market**

1. **Having your own local** branch (creation, merger/JV or acquisition): this approach involves the registration of your subsidiary and products in order to bring your products to Brazil or Mexico. This option is usually slow and costly (medical staff hiring, etc.) and best justified for proven markets and businesses with high investment capacity and international infrastructure.
2. **Using a local distributor:** you will need to find and negotiate with a local distributor knowing that it usually carries several competing brands and often focus on one region or state. Statistically, this option most of the time, results in failure within 24 months and becomes very costly.
3. Joining forces with a trusted third party recognized by ANVISA/COFEPRIS, **Mandala** (master distributor), get you up and competing faster and at much less cost with lower risk.

	Cost	Implementation	Risk Level
1 **Having your own local subsidiary**	High - Property investment(s), - Employing a doctor and/or pharmacist, - Business trips.	12 to 18 months - Creating a business structure, - Registering your affiliate, - Registering your products.	Medium - Legal risks (Brazilian/Mexican contract), - Salary and wage risks, - Commercial failure risks, - Autonomy, and independence.
2 **Outsourcing to one of your local distributors**	Moderate - Negotiating and ratifying a contract, - Often with a reference product and high commission, - Annual negotiation. Registration taxes can be paid by the local company	10 to 12 months - Language and translation barriers in carrying out your requests, - Lack of responsiveness and transparency from the distributor - Difficulties to train the distributor to your products	High - Legal risks (Brazilian/Mexican contract law), - Commercial risks (competing products), - Risks associated with the ownership of your registration (exclusive rights), - Obligation to rely on Distributor.
3 **Working with trusted third party specialized in regulatory issues (Master Distributor)**	Low - Presentation of a clear and accurate estimate, - Fixed amount per product (with discounts for multiple products),	8 to 10 months - Expedited process based and established relationship with ANVISA/COFEPRIS, - Your own dedicated bilingual contact, - Documentation and case management should be included, - Transparency and full autonomy.	Low - No salary, administrative or overhead costs, - Operated by a solid and trusted third party who can provide local assistance whenever you need it, - No exclusivity agreements, - Choice of commercial partners (local distributors) and control of sales volume.

The keys to your success in Brazil

MANDALA Brasil is a company specializing in the import-export business, whose aim is to facilitate access to the Brazilian market for all companies in the health and cosmetic sector.
MANDALA Brasil IS YOUR TRUSTED THIRD PARTY.

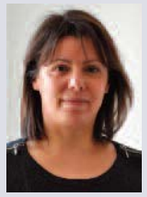
More than 25 experts worldwide at your service:

Daniel ROSENTHAL
President

Stephan FONTANEL
Vice President

Julie VISSEYRIAS
Chief Financial Officer

Benoît VISSEYRIAS
Chief Operating Officer



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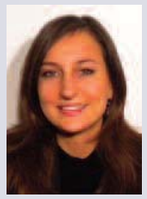

Alice MARTINIER
Marketing Department

Laura FONTANEL
Mexico Manager

Sabrina RIZZOTTO
Sales administration Manager

Plus: 4 Project Managers, 2 specialized translators/interpreters, 2 jurists, 1 IT Manager, 1 legal affairs manager…"

A reliable team with 12 years experience

MANDALA Brasil delivers a custom solution for the registration and integration of internationally manufactured health products and cosmetics (from France, Germany, UK, USA, China, India, etc.) within the Brazilian market.

Known and recognized by ANVISA for its competence and international compliance, MADALA's TEAM brings respect and credibility to the entire process of building relationships with regulatory agencies and distributors.

MANDALA Brasil has all licenses and accreditations to authorize us as an importer, exporter and distributor of health and beauty product. We use the best tools for monitoring and tracking the latest developments in Brazilian health legislation and regulation.

MANDALA Brasil - member of MANDALA International

MANDALA International is the world's leading consultant for innovative companies specializing in the medical/cosmetic sectors that seek guidance for their regulatory, financial, and administrative issues.

Whatever the size of your company or if you are already doing business in Brazil, MANDALA International will help you to optimize your development and investment.

MANDALA International is also:

→ **MANDALA Mexico** (the service is similar to the one offered in Brazil)

→ **MANDALA Service Provider:**
- Research and select distributors in every Brazilian or Mexican state.
- Provide Legal and regulatory analysis.
- Organize and register your company according to the various local requirements.
- Manage your local operation.

→ **CROFTHAWK & MANDALA Associés (France only):**
- Obtains public grants and financial incentives to facilitate export (specifically to Brazil and Mexico), innovation and R & D for cosmetic and medical products.
- Organizes the French Pavilion at the Hospitalar convention (Sao Paulo) in partnership with the French Trade Commission and Ubifrance.

MANDALA International is a trusted and reliable European company, recognized for its efficiency and expertise when it comes to South American markets.

Our solution

We aim to:

- **Become your regulatory partner,**
- **Be your administrative and commercial intermediary,**
- **Register your products and/or business using a recognized and local company,**
- **Keep and host your records and licenses,**
- **Import and distribute your products (medical devices, cosmetics, pharmaceutical, dental, sanitary products, and drugs, etc).**

This solution has many advantages:

- **You remain independent and autonomous,**
- **You choose all local distributors freely,**
- **You can determine for yourself when and how you want to sell your products (Master Distributor),**
- **We take care of your regulatory and administrative requirements,**
- **We bring you the guarantee of a European organization with a solid team of professionals respectful of legal and ethical principles.**

MANDALA Brasil also offers **two additional benefits** with our customized service:

Studying and Finding the right Distributors for you:

Do you want to better understand the market before you decide to invest there?

MANDALA Brasil delivers a specific three months assignment, including:

- A study of the market and specific business opportunities,
- Research and a selection of the best regional distributors (solid, reliable and authorized by ANVISA), specializing in your products,
- A study of financial and regulatory issues.

Our service includes a week in Brazil conducting face-to-face meetings with qualified local distributors and / or potential partners.

GMP and Quality Management:

Do you worry that your business must obtain a Certificate of Good Manufacturing Practice (GMP) and approval by ANVISA?

Because registration of your local subsidiary or distributor is required every two years, your company must maintain Certificate of Good Manufacturing Practice. An extremely detailed audit of the tools and methods of production you employ is conducted on your premises by ANVISA

MANDALA Brazil will perform a preliminary audit, complete with a technical report detailing our recommendations to guarantee compliance with all ANVISA requirements. (See "Our Procedures" opposite)

A proven approach, safe and secure

Brazil represents a huge potential market with **very strong growth** (PIB > 2Mds US $, population of 200 million, and was just ranked the world's sixth largest economy). But, it is also a **complex and impenetrable** market with strong protectionist regulations, which require substantial financial resources.

Optional pre-study:

→ Market and Distribution Survey [2]

- 3 months survey
- Meetings with future and potential partners, distributors, etc… for a week in Brazil

01.

→ First Meeting and Personalized Consultation

- Presentation of our sales teams and techniques.
- Examination and Corroboration of your penetration strategy, the products, and the market.

02.

→ Authorization to Carry Out a Preliminary Analysis

- Securing and Assessing the legal and economic framework.
- Pricing based on the number of products concerned.

03.

→ Audit and Preliminary Findings

- Determination of the product category (single, family, or system).
- Definition of regulatory prerequisites (registration or notification).
- Evaluation of classification within the definition of ANVISA, the National Health Surveillance Agency of Brazil. [1]
- Identification of other required certifications:
  – INMETRO, the National Institute of Metrology for products containing electronic components.
  – Certificates of Good Manufacturing Practice for registration requests.
- Clinical tests.

04.

→ Services and Contract

- Determination of fees for necessary registration or notification.
- Assessment of ANVISA taxes.
- A five-year economic business plan for hosting.
- Examination of all legal and regulatory requirements.

05.

→ Required Certification if applicable, such as a Certificate of Good Manufacturing Practice

- A preparatory meeting with ANVISA for an in-office consultation.
- Documented audit of manufacturing processes, production quality, and the supply chain.
- Inspection of the physical facility, including its structure, condition, appearance, equipment, hygiene and safety, and any environmental or structural remediation if needed.
- Preparation of technical report and recommendations.
- Management meeting to present the report for approval.
- Follow-up to review changes and recommendations.
- Preparation and filing of paperwork and applications to obtain proper certificate(s).
- Monitoring the application process to provide any additional information requested by ANVISA or other relevant agencies.

06.

→ Procedure for registration or notification

- Writing and developing appropriate presentation documents.
- Validating certifications.
- Filing and following up with relevant agencies.

07.

→ Publication in Brazil's "Official Journal of the Union"

- Proofreading and reviewing the consistency of the release, as well as registration certificates.
- Ensure the issuance of administrative documents.
- Start selling your product!

08.

→ Monitoring and Securing Business Environment

- Maintain records.
- Alert you to changes in regulatory requirements and certifications.
- Audit selected distributors to ensure legal compliance, ANVISA requirements, and financial health. [2]
- Issue and track Import Letters.

1 - The classification ANVISA differs from that of the FDA or CE.
Medical products are classified according to the **degree of risk that a patient runs** when using a product :

Notification:
Class I and Class II
Enregistrement:
Class I – low utilization risk, limited contact with the patient, e.g. bandages, anesthesia trolleys, compresses… etc.
Class II – higher risk for the patient / established contact with the patient, e.g. endoscopes, resins for dental surgery… etc.
Class III – high risk / body implants, e.g. orthopedic implants, bone resins… etc.

2 - As a holder of the registry, we validate the ability of your distributors and buyers to market your products. We will also provide you with a list of reliable and trusted distributors, who may be interested in your products, on request.

ESTIMATE FOR ANVISA SERVICES

MANDALA International would be delighted to send you a personalized financial proposal for:

- **Registering and managing your products in Brazil and / or in Latin America,**
- **Identifying distributors in Brazil and monitoring their performance,**
- **Auditing your premises and infrastructures in order to prepare you to obtain your Certificate of Good manufacturing Practice.**

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MANDALA BRASIL

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