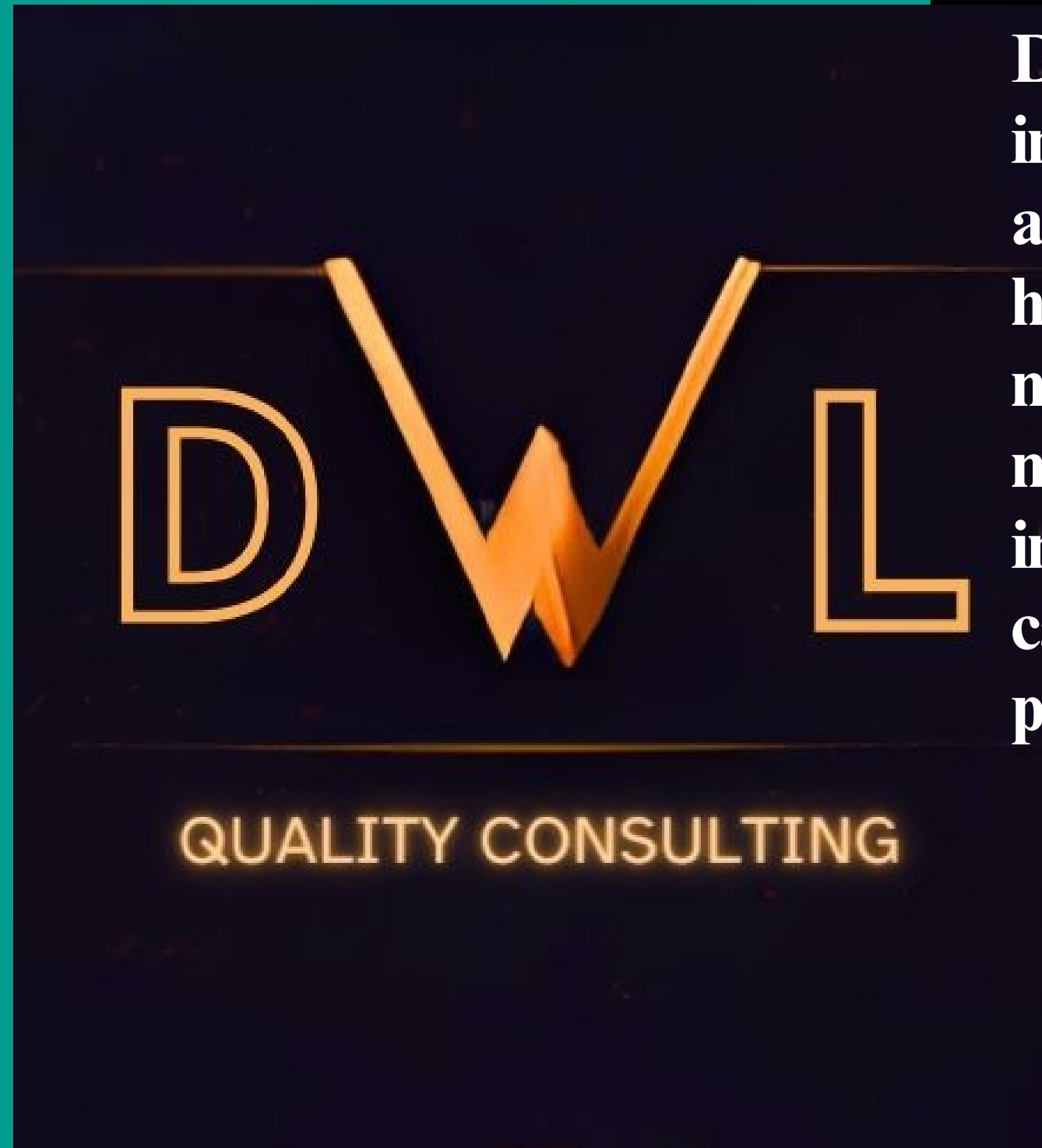


Promoting Compliance in the Brazilian Medical Equipment Market



About Us

DWL Quality Consulting has been a pioneering force in regulatory compliance for over a decade. Established at the inception of Brazil's regulatory standards, we have a proven track record of assisting foreign manufacturers in successfully entering the Brazilian market. Our expertise primarily serves manufacturers in Asia, and our extensive experience ensures that we can navigate the complexities of local regulations with precision and efficiency.

**Your Trusted Local Representative for
Medical Devices Certification**

Our Services for Medical Devices Manufacturers

As a leading Local Representative and Local Applicant for foreign manufacturers of medical equipment, our company ensures that your products meet the stringent standards set by ANVISA (the Brazilian Health Regulatory Agency) and comply with the requirements of Ordinance 384/2020. With comprehensive support, our expertise in navigating the regulatory landscape is extensive, making DWL your ideal partner in entering and thriving in the Brazilian market. Our services include:

- **Regulatory Compliance:** We guide you through the ANVISA registration process, ensuring your products comply to all necessary health and safety standards.
- **INMETRO System Management:** We operate Orquestra platform and assist with the certification process as mandated by Ordinance 384/2020, a crucial step for any medical device entering the Brazilian Market.

Our Services for Medical Devices Manufacturers

- **Local Representation:** As your Local Representant, we act as the primary point of contact with brazilian certification bodies, handling all necessary documentation and communication.
- **Certificate Holder Services:** As Certificate Holders, we maintain an open channel with the manufacturer's end customers, streamlining the bureaucratic process of obtaining Import Licenses. This ensures that everything is in place for the timely arrival of your products in Brazil.
- **Continual Support:** Our team offers ongoing compliance monitoring and support, ensuring that your products remain in good standing with Brazilian regulations.

The Brazilian Market

The Brazilian medical equipment market is one of the largest in Latin America, presenting significant opportunities for growth. However, entering this market requires strict adherence to local regulations. Having a trusted partner who understands the nuances of Brazilian law is essential for success.

Understanding Ordinance 384/2020

Ordinance 384/2020, issued by INMETRO (the National Institute of Metrology, Quality and Technology), establishes specific requirements for the certification of medical devices in Brazil. This ordinance is designed to ensure the highest level of safety and performance for medical equipment. Compliance with Ordinance 384/2020 is mandatory for market entry, and our team is adept at navigating these requirements, ensuring a smooth certification process for your products.

Ready to explore the Brazilian market? Let DWL Quality Consulting be your trusted partner in regulatory compliance and market entry. Contact us today to learn more about how we can help you succeed.

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DWL Quality Consulting: Pioneering Regulatory Compliance Since 2012

