

CASE STUDY

Emergo Brazil Helps Facilitate SprintRay's Global Expansion



Bringing a medical device into new markets can be a complex and daunting process. Registration, safety and performance requirements can vary from country to country. So when leaders at innovative digital dental device manufacturer SprintRay decided to expand into the Brazilian market, they knew just where to turn.

SprintRay was founded in 2014 in Los Angeles, California, and became an Emergo by UL customer in Australia in 2023. By hiring Emergo by UL as its Australian Sponsor, SprintRay streamlined its product registration process and released its devices in the Australian market in short order.

Growing rapidly, SprintRay was marketing its products not only in Australia but also in New Zealand, the U.K., Switzerland and Taiwan, and soon set its sights on the Brazilian market. It didn't take long for Dr. Sara Moghtadernejad, global director of Regulatory Affairs and Quality Assurance at SprintRay, to realize that engaging Emergo by UL as its Brazilian Registration Holder would help simplify the company's compliance efforts, manage language barriers and shorten the time to market for its advanced dental products that include a variety of resins that dentists and laboratories use to make ceramic crowns, veneers, dentures and surgical guides via 3D printing.



Solving pain points

Dr. Moghtadernejad listed the pain points that she expected the Emergo by UL team to address in helping SprintRay obtain regulatory approval from ANVISA, Brazil's National Health Surveillance Agency.

Challenges included:

- Finding a reliable Brazil Registration Holder
- Finding the correct category/product code in the ANVISA database
- Translating technical documents and completing the product registration application
- Efficient communication with local authorities due to time zone and language differences

Much like SprintRay's experience with Emergo by UL in the Australian market, the manufacturer is delighted with the service from Emergo by UL's team in Brazil. "They provide invaluable assistance during our project kickoffs, offering timely and useful information that helps guide the early stages of our work," says Dr. Moghtadernejad regarding the Emergo by UL team's efforts to overcome hurdles and optimize efficiency throughout the product registration process.

"The Emergo by UL team always addresses our questions with remarkable speed and expertise, whether it's related to document preparation, submission timelines or post-submission inquiries. They also take extra care to anticipate potential questions from ANVISA and makes sure they are proactively addressed before the final submission," Dr. Moghtadernejad adds.

Accelerating time to market

After addressing each of SprintRay's pain points, the Emergo by UL team helped shepherd the manufacturer's novel dental products through the complexities of compliance and onto the Brazilian market quickly.

The Emergo by UL team achieved these outcomes:

- Delivering Brazil Registration Holder service to SprintRay
- Providing a clear proposal and strategy at project kickoff
- Converting SprintRay's technical file documents into a comprehensive ANVISA application, including translation of instructions for use (IFU) and product specification documents
- Managing communication with ANVISA on behalf of SprintRay and successfully obtaining device approval within two months

The diverse expertise of the Emergo by UL team in Brazil helps the consultancy achieve a documented success rate of over 90% when assisting customers with device approval from ANVISA. In SprintRay's case, Emergo by UL helped register three products within four months and completed an amendment for one of the products within two months.

Service throughout the product life cycle

As a local authorized representative, Emergo by UL's relationships with customers don't end when the product is registered with the local regulators. Continuous communications keep customers informed of regulatory changes that could affect market access. If a customer shares with the Emergo by UL team that a modification has been made to a product, the team reassesses to determine whether the change warrants resubmission to regulators. Taking a proactive approach, Emergo by UL produces a steady stream of webinars, regulatory updates and email newsletters to keep customers up to date with all the latest regulations. In this way, Emergo by UL supports customers and helps them avoid disruptions in business operations.

