Establishment Labs Announces Certification of its Second Facility in Costa Rica

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Second manufacturing facility in Costa Rica has received certification and begun shipping units to Europe and around the world. This new site, in combination with the company's existing facility, extends manufacturing capacity by 4X and enables the company to expand its distribution capability.

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Establishment Labs, a global medical device company focused on aesthetic technologies with a strong emphasis on product development and innovation, announced today that its second manufacturing facility in Costa Rica has received its EC Certificate – Full Quality Assurance System from BSI and has begun shipping units from the new facility to Europe and around the world. This new site, in combination with the company's existing facility, extends manufacturing capacity by 4X and enables Establishment Labs to expand its distribution capability.

"Full Quality Assurance System certification of our new, state-of-the-art facility is an important milestone, as it not only reinforces the high quality standards of our entire organization, but also meaningfully increases manufacturing capacity, and enables us to fully supply expanding demand," said Juan José Chacón-Quirós, CEO and founder of Establishment Labs. "This certification is instrumental to our long-term strategic plans, provides compliance with key regulatory authorities, and adds significantly more flexibility to our current manufacturing and distribution operations. Our focus on product quality, state-of-the-art facilities, and deep technological know-how continues to establish and maintain our brand of consistency, quality and safety," concluded Chacón-Quirós.

"Designed and built with advanced, environmentally beneficial techniques, the building's infrastructure is supported by systems that are sustainable, renewable, and cost effective over the long term, such as a solar and battery microgrid, as well as an ice bank system that supports the clean room air systems," said Salvador Dada, Chief Operating Officer. "These were important considerations for us, and I am pleased that we were able to build a modern, environmentally friendly facility that meets the highest quality of standards."

The 40,000-square foot complex was completed in December 2016 and will serve as the company's corporate headquarters, hosting more than 300 people, including manufacturing, research & development, regulatory affairs, finance, customer service, and other operational functions. The facility is located in the Coyol Free Zone of Costa Rica, considered the largest and most modern high-tech business park in Central America, hosting medical device companies including Abbott, Medtronic, Philips, Smith & Nephew, and Cooper Vision, among others.

About Establishment Labs:
Establishment Labs is a global, privately held, medical technology company with a strong emphasis on innovation that designs, develops, manufactures and markets an innovative product portfolio. Its CE-marked Motiva Implants® line of silicone breast implants (http://www.motivaimplants.com) utilizes ultra-high purity medical-grade silicone and is subject to the strictest quality assurance testing throughout the manufacturing process. Motiva Implants® are sold in more than 60 countries worldwide. Puregraft®'s FDA cleared and CE-Marked technology provides plastic surgeons with purified fat for reinjection on the sterile field and is used in hospitals and clinics around the world. Divina® is a proprietary 3D imaging technology for full integration in consultation and surgical planning of unique solutions for breast aesthetics and reconstruction. All manufacturing facilities have been successfully inspected according to the MDSAP program for compliance with 8 of the most stringent standards and regulations, including ISO 13485 and FDA 21 CRF Parts 820 and 821.