Establishment Labs Obtains Medical Device Single Audit Program (MDSAP) Regulatory Certification

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Certification Assures Compliance with FDA Quality Management System (QMS) Regulation

NEW YORK, July 25, 2017 (GLOBE NEWSWIRE)

Establishment Labs, a global medical device company focused on aesthetic technologies with a strong emphasis on product development and innovation announced today that it has received the Medical Device Single Audit Program (MDSAP) regulatory certification of its two manufacturing sites in Costa Rica which are now in compliance with five regulatory bodies including the United States Food and Drug Administration (FDA).

"Establishment Labs is the first company in the aesthetics industry to obtain the MDSAP certification, which is a testament to the regulatory strength of our Quality Management System (QMS) in both manufacturing facilities in Costa Rica," said Juan José Chacón-Quirós, CEO and founder of Establishment Labs. "Now FDA compliant, these facilities will supply Motiva Implants® for our clinical trial programs in the United States and support our global expansion efforts."

MDSAP was established by a coalition of international medical device regulatory authorities including Australia's TGA, Brazil's ANVISA, Health Canada, Japan's MHLW and PMDA and the United States FDA. The goal of MDSAP is to allow a single regulatory audit of a medical device manufacturer's QMS to satisfy the needs of the participating regulatory jurisdictions. This program enables the manufacturers to contract with an authorized third-party Auditing Organization to conduct a single audit to satisfy the relevant regulatory requirements of the participating regulatory authorities including the FDA, which recognizes MDSAP audit reports as a substitute for FDA Establishment Inspection Reports (EIRs).

According to Salvador Dada, COO of Establishment Labs, "Certification of dual-production capabilities under MDSAP will help ensure continuity of supply for our customers and brings large scale capacity to support the growing demand for our Motiva Implants worldwide by achieving economies of scale as we expand our global offerings."

By obtaining this certification, Establishment Labs' QMS has been found to conform with ISO 13485:2003 (Medical devices – Quality management systems); Australia's Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding 1.6); Brazil RDC ANVISA N. 16/2013 (Good Manufacturing Practices for Medical Devices), RDC ANVISA n. 23/2012 (Reporting of Field Actions), RDC ANVISA n. 67/2009 (Post-market surveillance); Canada Medical Devices Regulations – Part 1 – SOR 98/282; Japan – MHLW Ministerial Ordinance 169 (Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and In Vitro Diagnostic Reagents), Article 4 to Article 68, Pharmaceutical and Medical Device Act (PMD Act); and USA – 21 CFR 820 (Quality System Regulation), 21 CFR 803 (Medical Device Reporting), 21 CFR 806 (Reports of Corrections and Removal) – Subparts A to D, 21 CFR 821 (Medical Device Tracking Requirements), for the design, production and distribution of silicone components and silicone implantable medical devices.

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 are fully compliant with both FDA and ISO applicable standards.

Motiva Implants and Divina are registered trademarks of Establishment Labs.