



Establishment Labs statement regarding TGA's regulatory actions in Australia

September 26, 2019

Establishment Labs Holdings Inc. (NASDAQ: ESTA) is a global medical technology company focused on women's health in breast surgery. Women are at the center of everything we do at Establishment Labs and it is our mission to protect their health by offering safe solutions in breast aesthetics and reconstruction. Based on those principles, a decade ago we began conducting research in conjunction with a risk analysis of breast implant safety, ultimately deciding never to manufacture macrotextured breast implants.

On September 26, 2019, the Therapeutic Goods Administration (TGA) in Australia confirmed that Motiva Implants® will not be affected by their investigations and the subsequent [regulatory action announced](#) in relation to breast implants and breast tissue expanders sold in Australia. As part of the new TGA requirements, Establishment Labs will provide additional information to practitioners and consumers in Australia and report adverse events for all of our breast implant and tissue expander devices sold globally.

Motiva Implants® are clearly differentiated from any other available traditional breast implants. Our SmoothSilk® / SilkSurface® shell is classified in the smooth category according to ISO-14607:2018 "Nonactive surgical implants - Mammary implants - Particular requirements", Annex H, Test for surface characteristics, which we had confirmed by independent testing conducted by Laboratoire National de Métrologie et d'Essais (LNE), a renowned third-party laboratory based in France. TGA's recent announcement is further affirmation of Motiva's differentiation.

We offer the most comprehensive portfolio of advanced smooth implants, which incorporates our proprietary SmoothSilk® / SilkSurface® nanosurface technology, which has been designed to minimize inflammation and maximize biocompatibility. This is one of just many safety features that we have built into our Motiva Implants® to improve patient safety and aesthetic outcomes.

Our entire portfolio of Motiva Implants® remain available in Australia and across more than 75 countries worldwide.

For additional information about our advanced product portfolio and breast implant safety features, please visit: [motiva.health](#)

Read our complete position statement on breast implant safety [here](#).