ISAPS INTERNATIONAL SOCIETY OF AESTHETIC PLASTIC SURGERY

Important Message for ISAPS Members

Friday, 2 October 2015

Suspension of Silimed's CE Certificate for Silicone Implants in Europe

New York, NY -- On September 23, 2015, news emerged that TüV Süd, a global testing, certification, inspection and training provider, was suspending the CE Mark for all products manufactured by the 37 year old Brazilian manufacturer, Silimed. The CE marking on a product is a manufacturer's declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation.

The suspension affects Silimed products in the European, Australian and New Zealand markets only. According to the Therapeutic Goods Administration (TGA), Australia's regulatory authority TüV Süd, gave the reason that potential particles identified as microscopic silica and cotton were identified during a routine inspection of one of Silimed's manufacturing facilities.

There is no information suggesting the identification of the potential particles represents any threat to patients.

ISAPS' Patient Safety Committee Chair, Dr. Lokesh Kumar says, "Silimed has been a partner with whom we have had a solid relationship with for many years. We are encouraged by the speed of their response in working with the appropriate regulatory authorities to investigate the incident and trust their efforts to find an acceptable solution. We are carefully monitoring the situation and will keep our members updated as soon as we have more information. However, based on what we know at present, the safety of patients who have Silimed or Sientra implants is not a risk. As Plastic Surgeons, patient safety is and always will be our top priority. We hope that this incident can be resolved by Silimed expediently and that the suspension will be lifted in due course."