

## Brazilian breast implant maker insists products are safe

## September 25 2015

A Brazilian manufacturer of breast and other implants insisted Thursday its products are safe, as several countries suspended their sale upon reports of contamination.

Health authorities in Britain, France, Switzerland and Australia have advised against the use of Silimed's products, which include <u>breast</u> implants, while tests are carried out by European Union regulators.

The move comes after a German audit detected foreign particles on the surface of <u>breast implants</u> in a Silimed plant in Brazil. The company's CE certification has been temporally suspended as a result, which bars it from selling its products within the EU.

"We emphasise that for the moment there has been no indication that these issues would pose a threat to the implanted person's safety," Britain's Medicines and Healthcare Products Regulatory Agency said in a statement.

"EU <u>health</u> regulators have initiated testing of samples of products to establish if there are any health risks," it added.

Silimed said it has "voluntarily" suspended the marketing of products on the European market until <u>health authorities</u> receive its official technical report and insisted that "the level of particles is extremely low and consistent with all markets."



"Our products are safe," the firm said in a statement to AFP. "There is no contamination of Silimed products, which are manufactured to the highest safety standards."

Silimed says it has been in the market for 37 years and that its <u>products</u> are approved for sale in 75 countries.

It added that in the EU "there are no criteria to define particulate levels, which can lead to a completely subjective analysis."

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