



***Siège social :*** EUROSILICONE S.A.S - Z.I. de la Peyrolière – B.P. 68 - 84402 APT CEDEX – FRANCE  
*Tél. : +33 (0)4 90 04 30 30 – Fax : +33 (0)4 90 04 60 06*  
*E-mail : [contact@eurosilicone.com](mailto:contact@eurosilicone.com) – site internet : [www.eurosilicone.com](http://www.eurosilicone.com)*

Apt, 22/12/2011

## **EUROSILICONE STATEMENT**

Eurosilicone are the largest manufacturer of Breast Implants in France and have been in business since 1988.

We are aware through the media of the reports associated with PIP and have no relationship of any kind with that organization.

Women with Eurosilicone products do not need to take any action.

Eurosilicone manufacture over 200,000 sterile medical devices annually at their facility in Apt, Provence, France. The breast implant products that we manufacture at the facility are CE marked, Class III, medical device products which is the highest classification according to the Medical Device Directive and therefore subject to the highest level of examination and quality. Our facility is regularly inspected by the authorities responsible for the certification of these products and we have continued to meet the quality and performance standards expected for all breast implant products.

We are in regular communication with the health authorities concerning our product vigilance and post marketing surveillance reporting requirements and continue to meet all of the commitments associated with marketing these products worldwide.

We are conducting on-going clinical trials on this product range in France and 5 year data to date shows a rupture rate of only 0.1% which is the lowest amongst all of the currently marketed breast implant products. We therefore believe that our products are the safest in the market and the patients can be confident in choosing Eurosilicone that they will perform as intended and meet their expectations and requirements.

We would recommend that concerned patients consult the current guidance of the French health authority (AFSSAPS):

[http://www.afssaps.fr/var/afssaps\\_site/storage/original/application/712400f4dcd8f705a62d5f3bf3c9b5d3.pdf](http://www.afssaps.fr/var/afssaps_site/storage/original/application/712400f4dcd8f705a62d5f3bf3c9b5d3.pdf)