



## ANSM information note translated by CEREPLAS

14/02/2014

As part of its inspection program concerning implantable medical devices , the National Security Agency of Medicines and Health Products ( ANSM ) has highlighted that some manufacturing activities carried out by the company CEREPLAS are not in accordance with current regulations .These include the control of the sterilization process and qualification of equipment used in production.

Commitments of compliance made by the company not being met, the ANSM has therefore decided to initiate a procedure of sanitary decision. This decision plans suspension of the placing on the market, exporting, distributing and using breast implants and corresponding sizers manufactured by the company CEREPLAS until compliance. It also plans for the withdrawal of these products.

CE marking certificates for these products have just been suspended by the notified body.

For devices covered by the decision and already on the market and implanted, the company CEREPLAS has brought elements leading not to jeopardize the safe use of the products.

The Agency has no evidence to suspect the existence of a sanitary risk concerning these devices used previously.