

Le Monde

4 janvier 2012

Distributors of PIP implants are addressing the certification body

They attack a mastodon, TÜV Rheinland, the certifying body prostheses PIP (Poly Implant Prosthesis) which were filled with gel non-medical, chosen by the company itself. Distributors of breast implants abroad are determined to make it clear that they are victims and not responsible. For the eyes of their clients, they are the representatives of the brand. Thus, in Venezuela, one hundred bearing prostheses were announced Friday, December 30, 2011, will turn against PIP, but also against its distributors to support the costs of replacing implants. The company PIP exported over 80% of its production. Worldwide, 300 000 to 400 000 women are concerned. Quietly, distributors have launched proceedings in December 2010. He first served a notice to TÜV for details on controls and issuance of certification, in the hope of an amicable settlement. If no response, they have assigned to the Commercial Court of Toulon in June 2011. Three distributors are responsible for this procedure: J & D Medicals for Bulgaria, for EMI Brazil and GF Electromedics for Italy. Since this summer, distributors Mexican, Thai and Syria have approached the trio. Others could follow. After an initial hearing September 15, 2011 before the civil court in Toulon, another is scheduled for February 2.

"Either by TÜV almost does not control how the implants were met, or he did his job and, in this case, there is a malaise," joked the lawyer of the three distributors, Mr. Olivier Aumaître, saying that while it is the reliability of the system of certification and control must be examined. The questioning of a certification body TÜV as is exceptional. It is on the quality and conformity of products guaranteed by TÜV PIP that customers have developed their business, said he. For a company, the certification of TÜV provides CE marking on his product, which is a "passport" for export. "We blame them for not doing their job, says Cedric Joachimsmann, J & D Medicals. If they are not responsible, then they are to what?" In November 2011, TÜV Rheinland recalled that it had filed a complaint against February 2011 PIP with the floor of Marseille. He accuses the PIP have "repeatedly misled", the company has always presented to the inspectors during inspections, "the silicone and compliant documents." The director of PIP, Jean-Claude Mas, acknowledged himself, speaking through his lawyer, Yves Haddad, December 28, 2011, knowingly deceived the inspectors during checks by exchanging the silicone in accordance with another type of silicone. The question is how the prestigious TÜV Rheinland has been tricked too rough? The answer is given by the body itself, which states on a simple "compliance check" on the product literature and on "the system of quality management" business, not "on the quality of the implants themselves." Proceedings "in full line with the standards," said TÜV, based on a European directive. "It certifying what then? Me Aumaître indignant. It is as if to certify a medication, we verified that he was divisible, it was not aspirin." He relies on a communication from the European Commission on breast implants, which stresses that "the risk analysis and conformity assessment shall cover the filler, the envelope and the implant." Retailers are wondering how TÜV could not detect anything in the accounts or by examining the source of the purchases.

They also question the fact that the organization has not conducted spot checks, as it could have done. For distributors, TÜV has an interest, it is solvent, whereas PIP, in liquidation, is not. The insurer of the company Var, Allianz, is also assigned to the Commercial Court by distributors. They also seek to know which agency has certified initially PIP products, in September 1997, TÜV, arrived in 2005. Large sums are at stake: more than 4 million euros for the Italian distributor, around 10 million for Bulgarian and Brazilian. Included in the estimates of damage the loss of value of existing stock in the immediate withdrawal from the market in 2010, lost revenue, damage to the image, and other compensation for patients. Retailers are not the only ones to turn against TÜV. In November 2010, the Association for the Defence of prostheses carry PIP (PPP) has filed a criminal complaint against the certifier for "endangering the lives of others and unintentional injuries." His lawyer, Philippe Courtois, surprised that the company "shall certify a product line, but does not pursue it." The lawyer of Marseilles four bearing prostheses, [Mr.](#) Lawrence Gaudon him, announced that he will appeal the judge of the court of Toulon against TÜV. "The organization has necessarily been negligent. They are supposed to control and they saw nothing," said he.