

## Press release: Decision of the Paris Court of Appeal in the scope of the PIP breast implants case



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Today, the Paris Court of Appeal handed down a decision in the scope of proceedings against TÜV Rheinland involving plaintiffs who claim to have received PIP silicone gel breast implants as well as foreign breast implants distributors.

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The Paris Court of Appeal has been referred with this matter in the scope of the appeals lodged by the notified body TÜV Rheinland LGA Products GmbH ("TRLP") and the company TÜV Rheinland France ("TRF") following the six decisions handed down by the French Supreme Court on October 10, 2018.

The Paris Court of Appeal exonerated any liability of the notified body TRLP and TRF with respect to many plaintiffs and dismissed the claims they had brought, notably for all the ones who were implanted prior to September 2006.

The Court of Appeal also dismissed the claims brought by many persons who do not prove that they wear or have worn the type of PIP silicone gel breast implants concerned by the fraud and covered by the certificates issued by TRLP.

However, the Court of Appeal considered that the liability of the notified body TRLP and that of the company TRF could not be fully excluded with respect to some plaintiffs as some pieces of evidence could have led TRLP to take additional measures as of September 2006.

"TÜV Rheinland notes that a great part of the claims have been dismissed by the Paris Court of Appeal but challenges its decision for holding the notified body liable, even partly. This decision goes against the decision of the Court of Justice of the European Union in February 2017 and that of the Versailles Court of Appeal in January 2021", said Maître Christelle Coslin, lawyer of TRLP and TRF in these proceedings. "The evidence in this case clearly shows that TÜV Rheinland acted diligently, in compliance with applicable regulations, and it was not its role to track down the fraud pursuant to regulation. In addition, the notified body reiterates that at no time in the scope of its mission he has been aware of elements suggesting that breast implants manufactured by PIP were not compliant".

TÜV Rheinland would like to emphasize that, on January 14, 2021, the Versailles Court of Appeal indeed ruled in similar proceedings that TRLP had not "breached its obligation of care and control in the performance of its certification mission carried out". It considered that the notified body TRLP has not been aware of any element relating to non-compliance of PIP implants and that "TRLP appropriately reacted to

the information it received". The Versailles Court of Appeal added that "TRLP cannot be blamed for not implementing additional measures", such as unannounced visits.

At European level, the Court of Justice of the European Union ruled in February 2017 that notified bodies, such as TRLP, are under no general obligation to pay unannounced visits, to examine products or to examine the manufacturer's business records.

In the scope of criminal proceedings, TRLP was found to be a victim of the fraud committed by PIP and its managers by the Marseilles Criminal Court in 2013, the Aix-en-Provence Court of Appeal in 2016 and then the French Supreme Court in 2018, which made this decision final.

**Background:** PIP deliberately manufactured silicone gel breast implants using – at least temporarily – a non-declared silicone filler gel. By way of a large-scale and particularly sophisticated fraud, PIP deceived all the parties involved: first and foremost women with PIP implants, but also health authorities and the notified body TRLP. PIP always declared that it only used the silicone gel that it declared to TRLP as raw material. PIP provided TRLP auditors with extensive documentation (design dossier, manufacturing records, manufacturing instructions) regarding the alleged use of the declared silicone gel. Any evidence or element concerning the use of different raw materials was systematically concealed by PIP.

As soon as PIP's fraud was discovered in late March 2010, TRLP suspended the certificates it had granted to PIP.

TRLP is very mindful of the concerns of women with PIP implants and shares their interest in PIP's criminal actions being cleared up. This is the reason why TRLP filed at the beginning of the case a criminal complaint against PIP and its managers. This has led to PIP and its managers being convicted in a final ruling as guilty of fraud against TRLP.

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