EU takes steps to improve breast implant safety

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The European Parliament on Wednesday adopted measures to improve medical safety in the wake of the worldwide scare over faulty breast implants from France.

The measures adopted after nearly five years of debate aim to ensure devices like breast and hip implants can be traced, meet EU patient safety requirements, and face tighter approval procedures.

The assembly in Strasbourg, France also approved laws to tighten up information and ethical requirements for diagnostic medical devices, such as pregnancy or DNA testing.

"We've introduced much stricter requirements for the bodies that authorise medical devices," said Glenis Willmott, a British member of the Socialists and Democrats group who steered the bill through the European Parliament.

Willmott said in a statement that supporters "will insist that particularly high risk devices, such as implants, joint replacements or insulin pumps, be subject to additional expert assessments before they can be authorised".

The measures, for example, require patients be given a card allowing them and doctors to trace which product has been implanted, the European Parliament said in a statement.

The conservative European People's Party, the largest bloc in parliament, said the new EU rules had been agreed on between Parliament and the 28 member states and will enter into force by mid-2020.

A court in the French city of Toulouse in January ordered German safety certifier TUV to pay 60 million euros ($64 million) in compensation to 20,000 women who received defective breast implants that the group had approved.

TUV Rheinland was ordered to make a provisional payment of 3,000 euros to each plaintiff for certifying that implants made by French firm Poly Implant Prothese (PIP) met safety standards.

In the far-reaching health scandal, the devices were later found to contain substandard, industrial-grade silicone gel that was seven times cheaper than medical-grade silicone.