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| R-TEAM-NB-Logo-2-0  **The European Association for Medical Devices of Notified Bodies** |

**European Medical Device Notified Bodies Statement on**

**European Medical Device Regulatory Regime**

The European Association for Medical Devices of Notified Bodies strongly condemn the behaviour of the medical device manufacturer Poly Implant Prothèse (PIP in committing deliberate fraud which led to high and unacceptable safety risks for patients. This case should serve as a stimulant to further improve the system of conformity assessment and surveillance of manufacturers by Notified Bodies as patient safety, public confidence, and ethical behaviour have always been the top priority of TEAM-NB members.

Team-NB fully supports the European Commission’s plan to implement immediate measures and at the same time strengthen the European medical devices legislation for the future

Team-NB has a firm belief that the principles enshrined in the current EU conformity assessment of medical devices can deliver an effective and efficient system combining direct Competent Authority market surveillance with elements of pre-market technical documentation review and on site surveillance in annual audits by Notified Bodies.

Team-NB recognises the need for some areas of improvement in the current European regulatory framework for medical device: harmonization of the supervision of the work of Notified Bodies ; Product Responsible Person; access to Post Market Surveillance data, content clarification of technical file in the legislation; product inspection; hotline (whistle blowing); unannounced visits,...

TEAM-NB are in the process of working with the EC Commission to achieve their objectives in the revision of the directives.

For further information please contact:

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